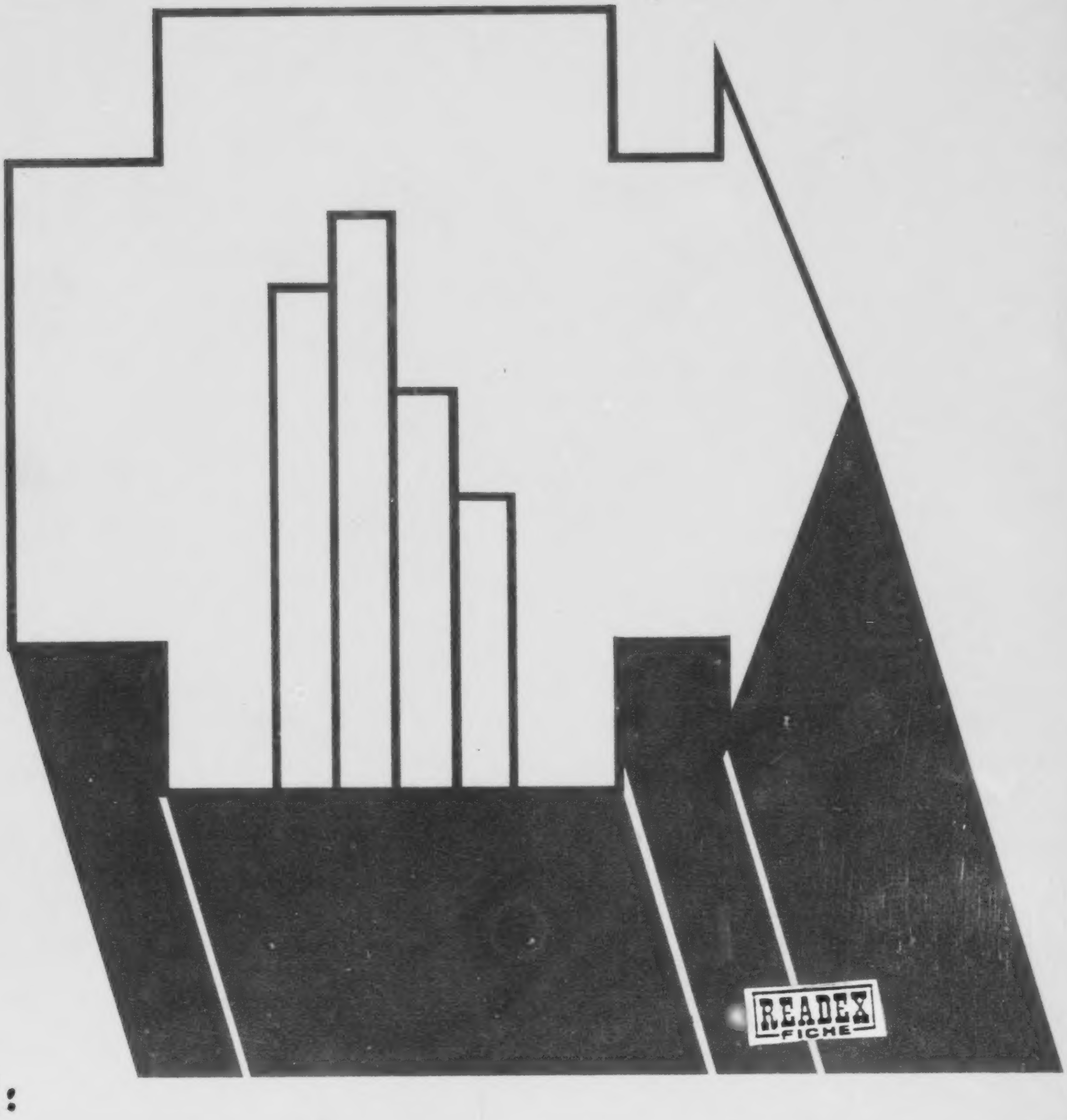
982

Medicare Annual Report

Fiscal Year 1982

NEWARK PUBLIC LIBRARY
MAY 20 1986
U. S. GOVT. PUBS.
DEPOSITORY 376



READEX FICHE

HE22.21:

Medicare Annual Report

Fiscal Year 1982

For sale by the Superintendent of Documents, U.S. Government Printing Office
Washington, D.C. 20402

SIXTEENTH ANNUAL REPORT
ON MEDICARE
COVERING FISCAL YEAR 1982

INCLUDING REPORTS ON THE

MEDIGAP VOLUNTARY CERTIFICATION PROGRAM

END STAGE RENAL DISEASE PROGRAM

TAX EQUITY AND FISCAL RESPONSIBILITY ACT

REPORT ON MEDICARE/MEDICAID VALIDATION SURVEY OF HOSPITALS ACCREDITED BY THE JOINT COMMISSION ON ACCREDITATION OF HOSPITALS

DEPARTMENT OF
HEALTH AND
HUMAN SERVICES

Health Care
Financing
Administration

Pursuant to the Social Security Act, as amended: Sec. 1875(b) (42 U.S.C. 1395ll (b)); 1881(g) (42 U.S.C. 1395rr(g)); Sec. 1882(f)(2) (42 U.S.C. 1395ss(f)(2))

TABLE OF CONTENTS

PAGE

Executive Summary..........

PART I CHAPTER I PROGRAM OPERATIONS.......... i
CHAPTER II PROGRAM ADMINISTRATION.......... ii
CHAPTER III RESEARCH, DEMONSTRATIONS AND STATISTICS.......... x

PART II END STAGE RENAL DISEASE (ESRD).......... xi

Introduction.......... xii

Part I
ANNUAL REPORT ON MEDICARE

Chapter I - PROGRAM OPERATIONS

A. Beneficiaries.......... 3

B. Health Care Resources.......... 3

C. Benefit Payments.......... 4

D. Claims Processing Performance.......... 6

E. Contractor Administrative Cost Experience.......... 10

F. Program Funding.......... 11

G. Contractor Performance Evaluation Program (CPEP).......... 12

Chapter II - PROGRAM ADMINISTRATION

A. Administrative Structure.......... 14

B. Achieving More Efficient Intermediary and Carrier Performance.......... 17

C. Reimbursement Controls/Policy Initiatives.......... 27

D. Improving Utilization Safeguards.......... 44

E. Quality and Appropriateness of Care.......... 48

F. Report on Medicare/Medicaid Validation Survey of Hospitals Accredited by the Joint Commission on Accreditation of Hospitals.......... 51

G. Increasing HMO Enrollment by Medicare Beneficiaries.......... 57

H. Fraud and Abuse Control Activities.......... 58

I. Beneficiary Services.......... 67

J. Medigap Voluntary Certification Program.......... 70

TABLE OF CONTENTS

PAGE

Chapter III - REPORT ON RESEARCH, DEMONSTRATIONS AND STATISTICS........ 74

Appendices

A. Part A Intermediaries and Part A Blue Cross Plans........ 92
B. Part B Blue Shield Plans and Part B Commercials, Other........ 96
C. Program Data by States........ 98
D. Five-Year Trend Analysis of Contractor Administrative Costs and Productivity Improvements........ 99
E. Significant Legislation Enacted During FY 82 Tax Equity and Fiscal Responsibility Act 103

PART II
END STAGE RENAL DISEASE (ESRD) PROGRAM - 1982

Chapter I - GENERAL

A Legislative Background........124
B. Scope of Report........125
C. ESRD Highlights........126
D. ESRD Program Growth........128
E. Data Collection........129

Chapter II - FACILITIES

A. ESRD Facilities Surveyed and Reporting by State in 1982....132
B. Number of Certified ESRD Facilities since 1973........134
C. Dialysis Facilities, Hospital - 1982........135
D. Dialysis Facilities, Independent - 1982........136
E. Type of Ownership - Profit vs. Non-profit - 1982........137
F. Minimum Utilization Rate Status of Facilities........138
G. Minimum Utilization Rate Status of Dialysis - 1982........140

Chapter III - DIALYSIS

A. Dialysis Patient Profile (Total, Incenter, Home, Self-Care).142
B. New Patient Characteristics (Total, Incenter, Home, New Starts)........149
C. Continuous Ambulatory Peritoneal Dialysis (CAPD) National Patient Registry........151

TABLE OF CONTENTS

PAGE

Chapter IV - TRANSPLANT

A. Summary of Transplant Activity....154
B. Transplants Performed During 1982 - By State....155
C. Transplant Types By Network - 1982....156
D. Transplants 1981 - 1982....157
E. Patients Awaiting Transplants vs Transplants Performed....158
F. Transplant Failures....159
G. ESRD Network Distribution of Transplants Arrayed by Number of Transplants Performed....160

Chapter V - COST

A. Hospitalization for Ancillary Problems....162
B. Kidney Acquisition Costs and Charges....165
C. Independent Organ Procurement Agencies....169
D. Dialysis Payment Rates....170
E. Changes In Dialysis Rates....170
F. Transplant Procedures....174
G. Physician Services....174
H. Projected Enrollment and Benefit Payments for the ESRD Program....176

Chapter VI - ESRD STATISTICS

A. Medicare Eligibility Status of Patients being Treated by Medicare Certified ESRD Facilities....178
B. Variation in Medicare ESRD Program Incidence by State....179
C. Mortality and Survival Rates....182
D. Mortality and Graft Failure Rates....188
E. Inpatient Utilization....196
F. Ratio of Patients Trained for Home Dialysis and Dialysis Patients Transplanted to Average Number of Dialysis Patients, 1979-1982....202
G. Major Reasons for Changes in the Number of Patients Treated by Medicare Certified Suppliers of ESRD Services, 1979-1982....203

Chapter VII - MISCELLANEOUS

A. Cost-Savings and Other ESRD Experiments....206
B. Results of Basic Kidney Disease Research....224
C. ESRD Network Organizations....239
D. Appendix - Tables and Figures....241

EXECUTIVE
SUMMARY
1982

ANNUAL REPORT ON MEDICARE

EXECUTIVE SUMMARY

This annual report describes the performance of the Medicare program during its sixteenth year. This report is divided into two parts: Part I, which provides an update on the Medicare program based on fiscal year 1982 activities and includes, Chapter I Program Operation, Chapter II Program Administration, which includes a new Report on Medicare/Medicaid Validation Survey of Hospitals Accredited by the Joint Commission on the Accreditation of Hospitals and the Medigap Voluntary Certification Program, Chapter III Research, Demonstrations and Statistics; and Appendix E which includes, the Tax Equity and Fiscal Responsibility Act (TEFRA) information and Part II, which reports on the End Stage Renal Disease program in calendar year 1982. These reports are mandated by the Social Security Act, as amended: Sections 1875(b), 1881(g), and 1882(f)(2).

PART I

CHAPTER I PROGRAM OPERATIONS

Beneficiaries - As of July 1, 1982, 26.5 million aged persons and 3.0 million disabled persons under 65, a total of 29.5 million persons, were entitled to Medicare. Of the 29.5 million enrollees, 29.1 million had hospital insurance (Part A) and 28.4 million had enrolled in the voluntary medical insurance program (Part B). Of beneficiaries aged 65 and over, 95 percent were covered by both Part A and Part B; 92 percent of disabled beneficiaries were covered by both parts.

Health Care Resources - As of July 1, 1982, there were 6,742 hospitals participating in Medicare, with 1,150,479 beds. There were 5,408 skilled nursing facilities, 3,415 home health agencies, 3,581 independent laboratories and 1,198 facilities or units providing services to program beneficiaries requiring maintenance dialysis or kidney transplant. Additionally, 419 rural health clinics had been certified to participate in the program.

Benefit Payments - During FY 82, Medicare paid $34.3 billion in benefits under hospital insurance (Part A) and $14.8 billion under medical insurance (Part B). These amounts represent an increase of 19 percent over FY 81 payments of $28.9 billion and $12.3 billion, respectively. Inpatient hospital care accounted for 95 percent of all Part A payments. Medical insurance payments were for physician and other Part B suppliers' services, accounting for 72 percent of Part B payments.

Claims Processing Performance - Claims received by Part A intermediaries increased to 47.3 million in FY 82, an increase of 5.3 percent over the FY 81 experience. Claims received by carriers rose at a rate of 9.7 percent, totaling 188.3 million in FY 82. Overall, the volume of Medicare claims rose 8.8 percent. The average claims processing time for intermediaries decreased from 9.5 days to 8.4 days. Carriers showed a decrease in average claim processing time from 12.2 days to 10.4 days. The average monthly percentage of bills pending over 30 days for intermediaries decreased from 16.3 to 13.7 percent. Carriers' average monthly percentage of bills pending over 30 days decreased from 13.9 to 11.4 percent.

Contractor Administrative Cost Experience - The FY 82 intermediary workload increased 7.1 percent over FY 81. The total cost decreased 1.1 percent. The unit cost for all operations decreased by 43 cents.

For carriers, the workload increased by 9.6 percent. The unit cost decreased by 19 cents during FY 82 and the total cost increased by 1.8 percent.

Program Funding - The primary source of hospital insurance financing is contributions, based on earnings, by workers and their employers, and by self-employed individuals. The remainder is derived from general revenues and other sources. Medical insurance (Part B) is financed by three sources: (1) premium payments from enrollees, (2) contributions from general revenues, and (3) interest on trust fund accumulations.

Rural Health Clinics

The Rural Health Clinic (RHC) Act was passed in the hope that defining this benefit under Medicare and Medicaid to allow payment for services, rendered by physician assistants and nurse practitioners, in RHC settings would expand the access to care for people in rural areas.

In FY 1982, $2,739,946 in Medicare benefits was paid to Rural Health Clinics. Administrative costs for RHC Medicare services were $993,854 which represents a 10 percent decrease from FY 1981.

Medicare intermediaries processed 234,177 RHC claims from an average of 421 RHC's.

PART I

CHAPTER II PROGRAM ADMINISTRATION

Administrative Structure - The overall responsibility for administration of Medicare is vested by law in the Secretary of the Department of Health and Human Services (DHHS); primary responsibility for administering the Medicare program is assigned to the Health Care Financing Administration (HCFA). The Social Security Administration is involved in the enrollment of beneficiaries in the program and other beneficiary related activities. The Department's Public Health Service (PHS) acts as a valuable resource in the professional health aspects of the Medicare program. The Office of Civil Rights is responsible for assuring compliance with Title VI of the Civil Rights Act of 1964. The Secretary also uses the services of appropriate State or local health agencies to determine whether providers of service and independent laboratories meet the conditions for participation in the Medicare program. Intermediaries (Part A) and carriers (Part B) contract with the Federal government to reimburse providers for services rendered to beneficiaries and to provide other services, in accordance with their agreements.

Intermediary and Carrier Performance - During FY 1982, HCFA evaluated the performance of Medicare contractors using the Contractor Performance Evaluation Program. In this program, specific standards and criteria were applied to all carriers and intermediaries. As a result, 10 Medicare contractors were identified as poor performers based on their performance during FY 1982.

Future contract renewal of 4 contractors was made contingent upon demonstrated improvements in performance. Six contractors received letters expressing concern about some area of performance. All ten contractors will be monitored closely in FY 83.

Contracting Initiatives and Experiments - Under Section 222 of P.L. 92-603, HCFA was granted experimental authority to test incentive contracting for intermediary and carrier administrative functions. Under an incentive contract, intermediaries and carriers are reimbursed on other than a cost related basis, rather than on actual costs incurred. They are at risk and may suffer monetary damages for failure to meet performance objectives. In addition, certain fixed price contractors also may receive incentive payments if their performance exceeds contractual requirements. As a result of assuming the risk of non-performance, intermediary or carrier internal management is responsible for improved efficiency and economy in operations. HCFA has taken action in the experimental contracts to assure that a continuing high level of service to Medicare beneficiaries and providers is maintained. In each experimental contract, performance requirements have been introduced which exceed those applied to the incumbent contractors reimbursed on a cost basis.

The use of incentive contracts on an experimental basis, authorized by Congress in 1972, is a departure from the basic statutory authority directing HCFA to reimburse contractors for the necessary and proper cost of administration of their contract duties. The experimental contracts utilize selected performance standards and existing quality control and performance review procedures and provide for the assessment of liquidated damages if the contractor fails to meet the standards established. Evaluations are made of actual performance against the standards and are completed on a quarterly basis by regional office staff.

Improving Utilization Safeguards - One of the most critical areas of Medicare program activity is to establish safeguards against improper and excessive utilization of health care services. The program has approached its responsibilities in this area in a number of ways, with its structure providing some fundamental controls. For example:

Deductible and coinsurance amounts.

Services furnished on a physician's order under direction of a physician.

Service reasonable and necessary for the diagnosis and treatment.

HCFA has continued to refine the pre- and post-payment screens which intermediaries and carriers utilize to identify situations of potential overutilization or variations from medical necessity norms.

REIMBURSEMENT CONTROLS/POLICY INITIATIVES

In FY 81, initiatives were undertaken to contain program costs without reducing the quality and accessibility of health care services to program beneficiaries. Of significance were:

Reasonable Cost Limits - Initially, provider reimbursement included all necessary and proper expenses incurred in the delivery of patient care. However, reimbursement based on incurred costs did not offer sufficient incentives to control the rapid escalation of health care expenditures. Section 223 of the Social Security Amendments of 1972 (P.L. 92-603) amended the definition of reasonable cost to exclude costs determined to be unnecessary in the efficient delivery of needed health services. Subsequent regulations authorized the establishment of prospective cost limits based on provider classification.

The reasonable cost limits were updated effective July 1, 1981, for hospitals and home health agencies and October 1, 1981, for skilled nursing facilities. The Omnibus Budget Reconciliation Act of 1981, enacted August 13, 1981, reduced the level of cost limits for hospitals and home health agencies for the period ending after September 30, 1981. Notices implementing these changes were published in the Federal Register on September 30, 1981.

Inpatient Routine Nursing Salary Cost Differential - Section 2141 of the Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35) reduced the inpatient routine nursing salary cost differential as a reimbursable cost of hospitals, to a "...rate not to exceed 5 percent..." effective October 1, 1981. The differential for SNFs remained at 8.5 percent. Regulations implementing this provision were published in the Federal Register on October 1, 1981. In FY 1982, TEFRA (P.L. 97-248) eliminated the inpatient routine nursing salary cost differential.

Reimbursement for Swing-Bed Services - On July 20, 1982, HCFA published regulations implementing the swing-bed provision (Section 904 of P.L. 96-499) of the Omnibus Budget Reconciliation Act of 1980. Under this provision, small rural hospitals with fewer than 50 beds which have been granted a certificate of need for the provision of skilled nursing and intermediate care services from the State, and which have an agreement with DHHS, can use their hospital beds interchangeably as either hospital, skilled nursing or intermediate care beds. Reimbursement is based on the specific type of care provided. The provision was added to increase the number of nursing home beds in rural areas.

Salary - Related Reimbursement of Certain Therapy Services - On March 26, 1982, a notice was published in the Federal Register updating the guidelines by a factor of 13.1 percent for services furnished on or after October 1, 1981.

OTHER POLICY INITIATIVES/ISSUES

Ambulance Services - Regulations were published as a Final Rule on September 16, 1982. These proposed regulations expand the ambulance benefit to include round trip transportation of a hospital and SNF inpatient to the nearest appropriate treatment facility to obtain necessary medical services not available in the hospital. The regulations specify that the availability of a physician or physician specialist capable of providing the treatment required by the beneficiary's condition is a factor in determining whether a hospital has appropriate facilities to care for the beneficiary.

Oxygen Therapy in the Home - A notice published in the Federal Register on December 14, 1979, contained proposed policies and guidelines that Medicare Part B contractors would apply, where necessary, to claims for oxygen used in the home. The objective was to assure that uniform criteria are applied by contractors in determining whether a valid medical need for oxygen exists so that the home use of oxygen can be paid for by the program.

Criteria and guidelines in this area are being reviewed within the Department.

Medicare Coverage of Heart Transplants - HCFA is undertaking a broad study of all aspects of medical coverage of heart transplantation, including social, economic, and scientific issues, in an effort to develop definitive national coverage policy. Heart transplantation is now excluded from coverage, effective June 13, 1980. This rescinded an earlier interim decision that authorized coverage only for heart transplants done at Stanford University Medical Center.

Medicare Coverage Decision Procedures - HCFA's process for developing national coverage policy determinations as to whether health care items and services are "reasonable and necessary" under the law has continued to improve. The HCFA Physicians Panel met regularly to discuss and advise on new and unusual questions, and to recommend referral of selected questions to the Public Health Service for medical and scientific advice and recommendations.

Section 210 of P.L. 97-35 (effective October 1, 1981) provided that Medicare Part B payment under Section 1861(s)(2) of the Social Security Act, and Medicaid payment under Section 1905(a)(12) of the Act, were to be prohibited for prescribed drugs for which the Secretary has issued a Notice of an Opportunity for a Hearing (NOOH) on a proposed order to withdraw the drug from the market because the FDA has determined that the drug is less than effective for all indicated uses.

Section 103 of P.L. 96-265 (effective December 1, 1980) provides that months from a prior period of disability benefit entitlement may be counted toward the 24 month Medicare waiting period for disability beneficiaries who become disabled a second time within 60 months of the cessation of previous entitlement to benefits (84 months for child's, widow's or widower's disability).

Section 104 of P.L. 96-265 (effective December 1, 1980) extended Medicare benefits for 24 months beyond the termination of the automatic disability benefit reentitlement period granted to disability beneficiaries who work despite the continuance of their disabling condition.

Confidentiality and Disclosure - HCFA prepared a final rule concerning certain regulations that concern the availability of Medicare information and records to the public. In addition to technical changes, HCFA changed its policy to allow disclosure of identifiable information without beneficiary consent to an individual or organization for epidemiological and other research and statistical purposes provided certain specific criteria and safeguards are met.

Provider Reimbursement Appeals - Section 955 of P.L. 96-499 amended Section 1878(f)(1) of the Social Security Act. The amendments make it possible for a provider that requests and has the right to obtain a hearing by the Provider Reimbursement Review Board (PRRB) under Section 1878(a) of the Act to bypass the hearing and obtain judicial review of any action of the fiscal intermediary that involves a question of law or regulations relevant to the matters in controversy, whenever the PRRB determines that it is without authority to decide the question. The PRRB may determine that it does not have the authority, either on its own motion or upon the request of a provider.

HCFA has published a regulation detailing the procedures by which a provider may bypass the PRRB hearing.

Waiver of Liability Procedures Applicable to Erroneous Placement in an Inappropriately Certified Bed of a Participating Hospital or Skilled Nursing Facility (SNF) - Section 956 of P.L. 96-499, effective January 1, 1981, amends Section 1879 of the Social Security Act to permit program payment for an otherwise qualified Medicare beneficiary who is precluded from Medicare reimbursement solely because services were received in a part of an institution not qualified to provide the appropriate level of care. This provision applies to hospital and SNF levels of care. Appropriate implementing instructions were issued to contractors and providers in FY 82.

Quality and Appropriateness of Care - A major goal of the Medicare program under the prospective payment system (PPS) is to assure the completeness and quality of care furnished to its beneficiaries. Under PPS, incentives may exist for unnecessary admissions, procedures, patient complications, insufficient hospital services, and premature discharges. To safeguard against these problems, HCFA will initiate review strategies to maintain or improve the quality of patient care in the Medicare system.

Standards and Certification - Facilities providing health care services to Medicare beneficiaries must meet certain health and safety standards before they can receive Medicare reimbursement. Annual surveys are conducted by States under contract with the Department. However, the Social Security Act allows the privately run Joint Commission on Accreditation of Hospitals (JCAH) and the American Osteopathic Association's (AOA) standards and certifications to be considered as having met the Federal government's requirements. Therefore, States survey only those hospitals not accredited by JCAH or AOA and, on a sample basis, conduct surveys on JCAH or AOA hospitals in order to validate that the surveys conducted by those associations continue to meet Medicare requirements.

Generally, the Federal Standards and Certification program is responsible for establishing and updating Federal health care standards, developing State survey procedures, and monitoring surveys and enforcement. This report includes discussion of major FY 81 activities in the following areas:

Hospital Conditions of Participation

Skilled Nursing Facility/Intermediate Care Facility Conditions of Participation

Survey and Certification Procedures (Subpart S)

Fire Safety Evaluation System

Conditions of Coverage for Suppliers of Laboratory Services

JCAH Validation Process

Professional Standards Review Organizations (PSROs) - As a result of the Omnibus Budget Reconciliation Act of 1981, PSRO's were no longer required to perform Medicaid reviews, effective October 1, 1981, but were still required to review those health services provided to Medicare patients. State Medicaid agencies were given the option of contracting with PSRO's for the continued performance of medical or utilization review functions and being deemed to meet the Utilization Control (UC) requirements for those services and providers that the PSRO reviews, or assuming direct responsibility for assuring the UC required by Title XIX of the Social Security Act. Any agreements entered into with the PSRO prior to October 1, 1981 continued to exist until the next renewal date of the agreement or in accordance with the instructions in the existing grant.

Second Surgical Opinion Program - In FY 78, HCFA began a major consumer information campaign to encourage all Americans to seek a second opinion before undergoing non-emergency surgery. The campaign was particularly directed toward Medicare and Medicaid beneficiaries. Public service announcements promoting the second opinion program and publicizing the national toll-free number (800-638-6833) were distributed to 730 television stations and over 6,000 radio stations. In fiscal years 81 and 82, nearly seven million brochures entitled "Thinking of Having Surgery? Think about Getting a Second Opinion." were distributed.

Increasing HMO Enrollment by Medicare Beneficiaries

Health Maintenance Organizations are a growing alternative to traditional forms of health care delivery. An HMO is an organization which provides its members comprehensive health services, without regard to frequency or extent of services, in return for predetermined, fixed premiums paid by members. During FY 82, 17 HMOs signed contracts to enroll Medicare members. This brought the total of contracting HMOs to 59. Medicare membership in HMOs increased during FY 82 from 66,238 to 90,198 or approximately 36 percent.

Fraud and Abuse Control Activities

During FY 79, the responsibility for full scale fraud investigations and prosecutions was transferred to the Department's Office of the Inspector General. As a result, HCFA began to focus attention on integrity reviews, abuse case processing, administrative sanctions activities, payment reviews, and increased efforts in various types of validation reviews.

In FY 82, 32,585 integrity reviews were processed by HCFA regional offices and Medicare contractors. Overpayments identified as a result of these reviews total $4.4 million. Additionally, 2,903 full scale abuse cases were processed by HCFA regional offices and Medicare contractors. As a result of these cases, $19.3 million in overpayments was identified.

In FY 82, action was taken to suspend 19 physicians/practitioners from participation in the Medicare program. Exclusion actions were taken against 23 providers, practitioners and/or health care suppliers.

During FY 82, HCFA continued its extensive validation review program to detect fraud, abuse, and waste among providers, and to identify and correct inappropriate and potentially wasteful policies and procedures. During FY 82, 135 final validation reports were produced which identified total Medicare overpayments or other program savings of $51.3 million.

Beneficiary Services

The Office of Beneficiary Services was established in December 1979, with the primary objectives being to;

1. Inform beneficiaries about HCFA programs, and their rights and responsibilities.
2. Open channels of communication between beneficiary representative groups and HCFA.
3. Improve services provided to beneficiaries by contractors, State agencies and Social Security offices.

Medigap

HCFA has developed an education program to better inform Medicare beneficiaries about (1) Medicare coverage, (2) the major gaps in Medicare coverage, (3) the various types of private health insurance designed to supplement Medicare and (4) comparative shopping hints to use when purchasing private supplemental health insurance. To implement this initiative, OBS designed, developed, and produced the 68-page training text, Medicare and Private Health Insurance, based on a pamphlet developed jointly with the National Association of Insurance Commissioners (NAIC). This text, plus accompanying visual aids and a checklist for comparing policies, served as the basic material for a nationwide program to train counselors and volunteers who, in turn, assist Medicare beneficiaries on private health insurance decisions. To date, HCFA Regional Office Medigap coordinators (who received their initial Medigap training at central office) have conducted more than 470 training sessions in all 50 States, the District of Columbia and Puerto Rico. Approximately 22,000 attendees have received Medigap training through this program. A continuation of another facet of the Medigap initiative has been the distribution of over 9 million copies of A Guide to Health Insurance for People with Medicare, the information pamphlet which was first produced in 1979 in conjunction with NAIC.

Updating, Revising, and Improving Beneficiary Informational Material

OBS revises and updates Your Medicare Handbook semi-annually and all other Medicare pamphlets at least annually. Six million copies of Your Medicare Handbook were printed and distributed to Social Security Offices, Medicare contractors and new Medicare enrollees during FY 1982.

When major changes in the Medicare program occur, a new pamphlet is often printed. Recent Changes in Medicare was prepared during FY 1982 because of special informational needs created by the 1980 and 1981 Reconciliation Acts.

OBS also helps the public stay informed about current changes through Medicare/Medicaid Notes which is a monthly fact sheet explaining specific issues or recent changes in Medicare or Medicaid policy and procedures. This is distributed to all HCFA Regional Offices and approximately 40 National organizations (e.g., American Association of Retired Persons and National Council of Senior Citizens which have publications or newsletters for their members).

Beneficiary Casework

OBS continued to function as a central office ombudsman for special beneficiary inquiries and problem cases. Most inquiries are telephone referrals from the Office of the Administrator, HCFA Office of the Secretary, HHS, the White House and Congress. Many inquiries come directly from beneficiaries seeking help with errors in their records resulting in loss of eligibility or incorrect premium billings necessitating a review and correction of their Medicare records. There is also a high incidence of complaints about what are seen as deficiencies in program coverage; e.g., the lack of prescription drug or nursing home coverage under Medicare. In such cases, efforts are made to guide the caller to other resources for financing the necessary medical services. Other inquiries relate to difficulties with Medicare contractors and problems involving submission of, and reimbursement for, Medicare claims. In all these instances, the ombudsman function provides a valuable service for Medicare and Medicaid beneficiaries, many of whom have difficulty dealing with the complexities of these programs.

Liaison With Beneficiary Organization

OBS maintains an ongoing program of liaison with beneficiary organizations. In addition to soliciting beneficiary organization input and participation in the development of program policy procedures through briefings and personal liaison, OBS periodically mails materials to national beneficiary groups to keep their membership informed about current Medicare benefits and coverage. OBS representatives also attend national organization conferences and meetings, and participate in workshops, panel discussions and forums on Medicare-related issues.

Beneficiary Services Awards

The Beneficiary Services Awards were established to provide special recognition to individuals or groups for either outstanding performance in service to beneficiaries or for a major contribution in the area of beneficiary services. The awards serve to provide an incentive to develop innovative ideas, resources, and programs in assisting beneficiaries. OBS recognized outstanding beneficiary service again in FY 1982 as part of HCFA's Annual Awards Ceremony. The Beneficiary Service Certificate of Merit was presented to four HCFA employees and ten non-government employees for their contributions to the improvement of services in the Medicare and Medicaid programs. This final group of ten represented Medicare contractors, State agencies, and beneficiary groups from ten different States.

PART I

CHAPTER III RESEARCH, DEMONSTRATIONS AND STATISTICS

Research and experimentation in support of the Medicare program is authorized in the Social Security Act and the Social Security Amendments of 1967 and 1972, as well as in the National Health Planning and Resources Development Act of 1972.

HCFA studies and develops ways to promote efficiency and quality in the Medicare and other HCFA programs. It assesses the impact of HCFA programs on health care costs, program expenditures, beneficiary access to services, health care providers, and the health care industry. These research and demonstration projects test and evaluate alternatives to present reimbursement, coverage, eligibility and management policies of the Medicare program.

During FY 82, HCFA conducted research, demonstration and evaluation projects in the following nine program areas:

Beneficiary Impact and Awareness

Health Systems Organization

Hospital Costs

Industrial Organization and Reimbursement

Integrated Data Management Systems

Long Term Care

Physician Reimbursement

Program Evaluation

Quality and Effectiveness

Following the section on the research, demonstration and evaluation projects, there is a brief discussion of HCFA's data base and statistical activities. There is also a discussion of the research and demonstration publication program. Copies of the publications are available from ORD Publications, Room 2-E-6 Oak Meadows Building, 6340 Security Boulevard, Baltimore, Maryland 21207.

LEGISLATION ENACTED IN FY 82

The only significant piece of legislation affecting Medicare which was enacted during FY 82 was the Tax Equity and Fiscal Responsibility Act of 1982, P.L. 97-248. This new public law includes many provisions which impact the Medicare program. A summary of changes is attached at Appendix E.

PART II

ANNUAL REPORT
ON THE

END-STAGE RENAL DISEASE PROGRAM
(CALENDAR YEAR 1982)

PART II

END STAGE RENAL DISEASE

The End-Stage Renal Disease (ESRD) part of the report is prepared in accordance with Section 1881(g) of the Social Security Act, and addresses the 15 specific requests for data enumerated therein. It covers activities related to the care of ESRD patients that took place in calendar year 1982, and includes information on the number of patients utilizing the various forms of treatment, the costs involved, discussions of cost savings experiments, and basic kidney research conducted during the year.

The total dialysis population increased by 11.6 percent in 1982, to 65,765 from 58,924 in 1981. The home dialysis population increased by 23.9 percent, to 11,733 from 9,474 in 1981. The net increase in home patients was due largely to the growth of continuous ambulatory peritoneal dialysis (CAPD) from 4,347 patients in 1981 to 6,523 patients in 1982. CAPD now accounts for 55.6 percent of all home patients. At the end of 1982, the home dialysis population accounted for 17.8 percent of the total dialysis population, a net increase of 1.7 percent over 1981.

The number of transplants performed increased by 9.7 percent in 1982, to 5,358 from 4,885 in 1981. Patients transplanted in 1982 accounted for 7.0 percent of the total ESRD population, a net decrease of 0.7 percent over 1981. The percentage of total transplants performed with kidneys from living related donors increased to 15.0 percent over 1981 figures, while cadaveric transplants increased 7.4 percent.

Total expenditures for services rendered during calendar year 1982 were more than $1.6 billion, based on bills posted as of December 31, 1982. The 1982 figure will increase as bills continue to be posted. The average payment rate for both hospital and freestanding dialysis units for dialysis was $156 per treatment without physicians' fees. The average kidney acquisition charge in 1982 was $9,009 for a living related donor kidney and $8,818 for a cadaveric kidney. The average estimated kidney acquisition costs were $7,769 and $7,636, respectively. The average estimated cost for a transplant in 1982 was $26,036, excluding physicians' services.

INTRODUCTION

This annual report on Medicare, the sixteenth, describes program performance from October 1, 1981 through September 30, 1982. For the first time, additional reports mandated by Congress are included: Tax Equity and Fiscal Responsibility Act (TEFRA), Report on Medicare/Medicaid Validation Survey of Hospitals Accredited by the Joint Commission on Accreditation of Hospital (JCAH), and Medigap Voluntary Certification Program.

In fiscal year 1982, the Federal government continued to place high priority on combating inflation and reducing public expenditures. Attention to these objectives is reflected throughout this report by the considerable emphasis on increasing operational efficiency of medicare and improving the effective use of public funds for this major national health care program.

PART I

ANNUAL REPORT ON MEDICARE INCLUDING REPORTS ON

THE MEDIGAP PROGRAM

THE TAX EQUITY AND FISCAL RESPONSIBILITY ACT

THE MEDICARE/MEDICAID VALIDATION SURVEY OF HOSPITALS ACCREDITED BY THE JOINT COMMISSION ON ACCREDIATION OF HOSPITALS

CHAPTER I. PROGRAM OPERATIONS

A. BENEFICIARIES

As of July 1, 1982, 26.5 million aged and 3.0 million disabled persons under 65 (a total of 29.5 million) were covered by one or both parts of Medicare. Of all enrollees, 28.9 million resided in the United States, representing 12 percent of the U.S. resident population. Of the total 29.5 million enrollees, 29.1 million had hospital insurance protection (Part A), and 28.4 million had enrolled in the voluntary medical insurance program (Part B). Of beneficiaries age 65 or over, 95 percent were covered by both Part A and Part B; 92 percent of disabled beneficiaries were covered by both parts.

The number of aged persons entitled to Medicare as of July 1, 1982 increased by 530,000 (from 26.0 million to 26.5 million) over the July 1, 1981 enrollment. This increase reflects the continuing trend of the last decade in an annual net growth of over 2 percent in the age 65 and over segment of the U.S. population. In addition to growth in the number of aged, the average age of beneficiaries also increased. The proportion of beneficiaries age 85 and over increased from 7 percent in 1970 to 9 percent in 1980. In addition, there has been a 10 percent decline in the death rate of the 65 and older group from 1970 to 1980. The death rate in 1970 was 5,892 per 100,000 as compared to 5,291 per 100,000 in 1980. These factors contribute to more intensive use of Medicare-covered health care services over a longer period of time.

B. HEALTH CARE RESOURCES

As of July 1, 1982, there were 6,742 hospitals participating in Medicare, with 1,150,479 beds. Included in the participating hospitals were 6,070 short stay hospitals, 419 psychiatric, and 253 other long stay institutions. Eighty-eight percent of the total number of beds are in short stay hospitals, 10 percent in psychiatric institutions.

As of July 1, 1982, there were 5,408 skilled nursing facilities with 488,495 beds participating in Medicare, up from 5,258 facilities with 457,692 beds as of July 1, 1981. Participating facilities include skilled nursing facilities, separately organized extended care units in hospitals, and some separate skilled nursing units connected with residential homes for the aged.

The number of home health agencies participating in the Medicare program rose from 3,110 to 3,415 in the 12-month period ending July 1, 1982.

As of July 1, 1982, a total of 3,581 independent laboratories had been approved for Medicare reimbursement, up from 3,484 12 months earlier. There are 21 reimbursable categories of clinical tests or procedures. Laboratories can be reimbursed by Medicare only for those tests which they are certified to perform.

Under the renal disease program, as of July 1, 1982, 1,198 facilities or units provide services to program beneficiaries requiring maintenance dialysis or kidney transplant. Of the participating providers, 688 were hospital based and hospital operated. Of this number 382 were hospital units certified as Renal Dialysis Centers only and provide the full spectrum of diagnostic, therapeutic, and rehabilitation services required for the care of dialysis patients; 8 were hospital units approved as Renal Transplant Centers only and provide transplantation and other medical and surgical specialty services required for the care of transplant patients; 147 were hospital units certified as both Renal Transplant Centers and Renal Dialysis Centers; 117 were units approved to furnish dialysis services; and 34 were hospitals certified to provide backup dialysis services. The remaining 510 facilities were certified as free-standing, dialysis-only facilities.

A new category of health care facility was added by the Rural Health Clinic Services Act of 1977 (P.L. 95-210). By July 1, 1982, 419 rural health clinics had been certified to paticipate in the Rural Health Clinic Program.

C. BENEFIT PAYMENTS

During FY 82, Medicare paid $34.3 billion in benefits under hospital insurance (Part A) and $14.8 billion under medical insurance (Part B). These amounts represent an increase of 19 percent over FY 81 payments of 28.9 billion and $12.3 billion respectively. Almost half of the amount of the increase resulted from increases in hospital costs and higher physician fees recognized by the program. Studies discussed in Chapter III of this report indicate that price inflation contributes most to these increases. The remainder of the increases were due to such factors as utilization of more expensive technology in health care delivery, increasing rates of utilization of services, and increases in both the number of aged beneficiaries and the proportion of persons aged 75 or older within the aged population. The latter group requires more medical services and more frequent hospitalization for longer periods of stay.

Inpatient hospital care accounted for 95 percent of all Part A payments. The program also covers convalescent care after a hospital stay of at least three days either by direct transfer to a skilled nursing facility or through home health services. Benefit payments for these two levels of extended care services represented 5 percent of total Part A payments.

Medical insurance payments were predominantly for physicians' and supplier services accounting for 72 percent of Part B payments. The next highest reimbursed category was outpatient services (20 percent), followed by inpatient services furnished by radiologists and pathologists (5 percent), group practice prepayment plans (2 percent), and laboratory services (1 percent).

Inpatient Hospital Services

During FY 82, approximately 113 million inpatient hospital days were approved for payment. The aged accounted for 88 percent of the total, while the remaining 12 percent were for the disabled. The rate of covered days of care per 1,000 enrollees was about 3,750 for the aged and 4,500 for the disabled. In FY 82, hospitals were paid $32.7 billion for Part A benefits, 95 percent of all Part A payments.

Skilled Nursing Facility Services

During FY 82, 8.1 million days in skilled nursing facilities were approved for payment, 7.9 million were incurred by the aged and 0.3 million by the disabled. This represents an annual rate of 300 covered days per 1,000 aged enrollees and 100 covered days per 1,000 disabled enrollees. Benefits paid totaled approximately $454 million or 1.3 percent of total Part A payments in FY 82.

Home Health Services

Almost 30 million visits provided by home health agency personnel were approved for payment during FY 82, an average of 1,000 visits per 1,000 aged enrollees and 800 per 1,000 disabled enrollees. Home health service benefit payments under both hospital and medical insurance totaled $1.2 billion for FY 82 representing 2.4 percent of total Medicare benefit payments.

Physician and Other Part B Supplier Services

For FY 82, medical insurance payments for physicians (excluding inpatient radiology and pathology services) and other Part B suppliers totaled $10.6 billion, about 72 percent of total Part B payments.

Radiology and Pathology

Payments in FY 82 for inpatient services furnished by radiologists and pathologists amounted to $742 million or 5 percent of Part B payments.

Other Medical Services and Suppliers

For FY 82, approximately $308 million was paid to group practice prepayment plans, $2.9 billion for outpatient services and $175 million for independent laboratory services.

Telephone Directory Listings Under Medicare

In July 1982, all Medicare Part B contractors were instructed to have their local and toll-free telephone numbers displayed with "Medicare" in the White Pages of the telephone directories which cover their service areas.

SSA District Office Final Adjudication of ESRD Initial Claims

In November 1981, the SSA district offices were given the capability to take final adjudicative action on certain initial end stage renal disease (ESRD) awards. HCFA proposed this change in procedure and coordinated its implementation with SSA. District office final authorization has resulted in a decrease in processing time for initial ESRD awards. Many ESRD patients now have Medicare records established more quickly and medical bills for dialysis or transplant can be processed with less delay.

Centralization of the Direct Billing and Collection Operation

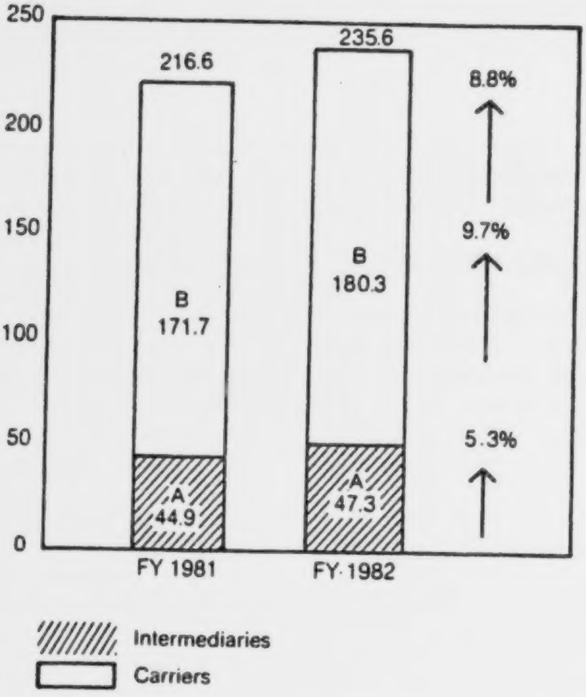
Until September 1982, the Social Security Administration (SSA) printed and mailed bills from its Baltimore headquarters to 825,000 Medicare beneficiaries who are billed directly for their Medicare premiums. These punch card bills and premium payments were then returned to eight different SSA Program Service Centers for processing. This punch card operation converted to a centralized lockbox (all premiums paid and processed by a private bank) operation. The beneficiaries were provided a portion of the new bill as a receipt, the bill is easily readable and is processed using automated equipment. The beneficiaries now receive the bills at least 5 days earlier and all funds collected by the lockbox bank are deposited to the Treasury Department within 72 hours. The conversion of the operation to a lockbox bank resulted in yearly savings of about $1,550,000.

D. CLAIMS PROCESSING PERFORMANCE

Claims receipts--The volume of Medicare claims received continued to increase through FY 82. Contributing to this upward trend were the steady increase in the number of covered beneficiaries, increased utilization of covered services, and the tendency of beneficiaries to submit claims for each bill or service received rather than accumulating them for periodic submittal. Claims received by Part A intermediaries increased to 47.3 million in FY 82, an increase of 5.3 percent over FY 81 experience. Claims received by carriers rose at a rate of 9.7 percent, totaling 188.3 million in FY 82. Overall, the increase in Medicare claims was 8.8 percent.

Claims Received by Medicare Contractors

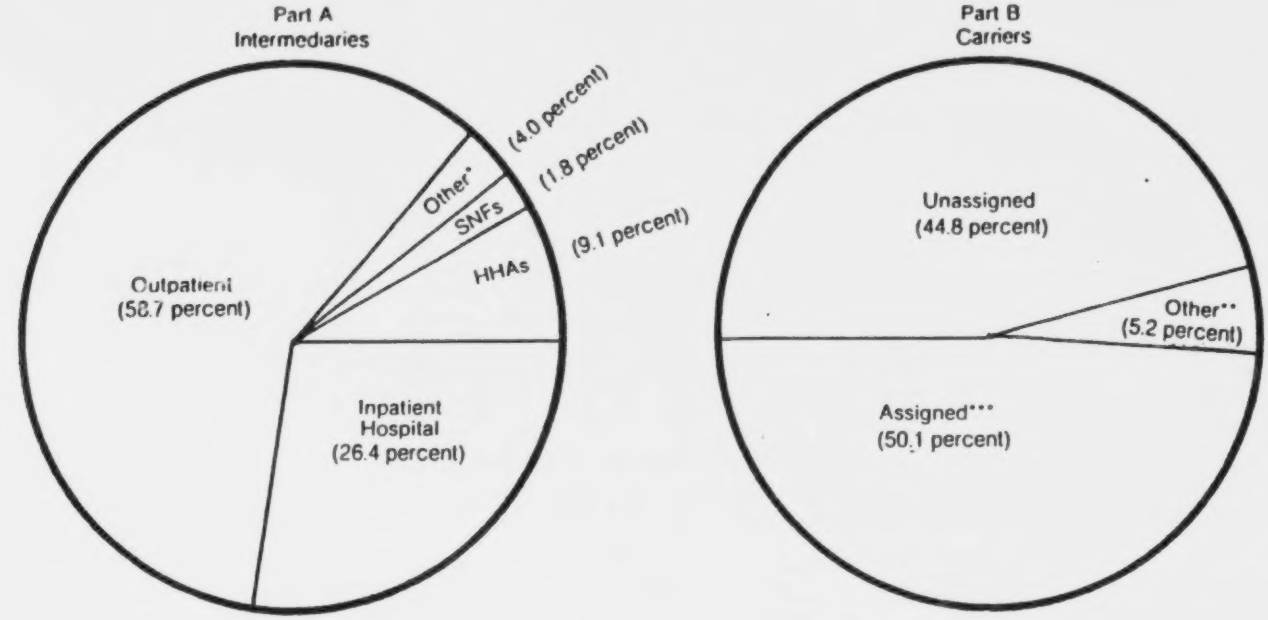
(millions)



Distribution of Claims - The majority of claims received by intermediaries during FY 82 represented requests for payment for outpatient services provided Medicare beneficiaries. These claims accounted for 58.7 percent of the total received by intermediaries. Inpatient hospital claims accounted for 26.4 percent of the receipts while claims for home health agency and skilled nursing facility services represented 9.1 percent and 1.8 percent, respectively. The remaining 4.0 percent were claims submitted for ancillary and other miscellaneous services payable under Part B.

Claims received by carriers during FY 82 were nearly equally divided between those submitted by physicians and suppliers on assignment (50.1percent) and the combined total of those submitted unassigned by beneficiaries (44.8 percent) and those submitted by provider-based physicians and group practice prepayment plans (5.2 percent). In comparison to FY 81 experience, the percent of assigned claims to total claims showed a slight increase of 0.7 percentage points.

Distribution of FY 82 Receipts by Type of Claim



* Ancillary and other miscellaneous services payable under Part B.

** Claims for services provided by provider-based physicians and group practice prepayment plans, who do not bill patients directly.

*** This represents the assignment rate measured against all claims. When measured only against claims in which patients are billed directly (i.e., excluding the 5.2 percent of claims for provider-based physician services and group practice prepayment plan services), the assignment rate in FY 82 was 52.8 percent, the figure usually quoted as the Medicare Assignment rate. This is a slight increase over FY 81 assignment rate of 52.2 percent.

Claims Processing Timeliness--When compared to FY 81 experience, the timeliness measures of contractor claims processing performance in FY 82 indicated an overall improvement for both Part A intermediaries and Part B carriers. The average processing time for intermediaries decreased from 9.5 days to 8.4 days, and the average monthly percentage of bills pending over 30 days decreased from 16.3 percent to 13.7 percent. Carriers showed a decrease in yearly average claim processing time from 12.2 days to 10.4 days. Over the same time period the average monthly percentage of claims pending over 30 days for carriers decreased from 13.9 percent to 11.4 percent.

Intermediaries

	Contractor Processing Time (Mean Days)		Percent of Claims Pending Over (30 Days)	
Quarter	FY '81	FY '82	FY '81	FY '82
1	9.3	8.5	16.5	14.7
2	9.5	9.5	13.9	14.7
3	9.5	8.1	17.6	13.5
4	9.8	7.3	17.2	12.0
Yearly Average	9.5	8.4	16.3	13.7

Carriers

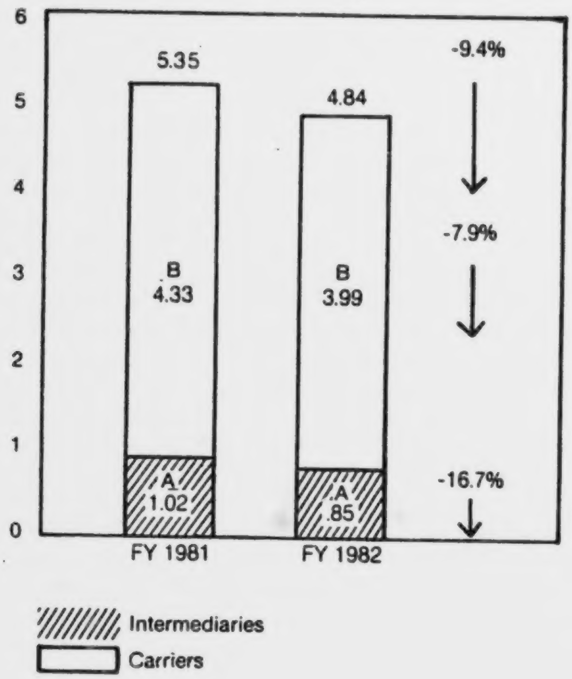
	Contractor Processing Time (Mean Days)		Percent of Claims Pending Over (30 Days)	
Quarter	FY '81	FY ' 82	FY '81	FY '82
1	11.9	10.2	13.0	12.9
2	13.8	11.9	13.7	12.0
3	11.6	10.2	15.2	9.0
4	11.5	9.6	13.4	10.8
Yearly Average	12.2	10.4	13.9	11.4

Claims Pending

Intermediaries experienced a decrease in the volume of pending claims in FY 82 compared to FY 81, with a 16.1 percent decrease to 850,000 claims. Part B carriers' pending claims in FY 82 showed a decrease of 7.9 percent from FY 81, when there were 4.33 million pending claims.

Claims Pending for Medicare Contractors

(millions)



E. CONTRACTOR ADMINISTRATIVE COST EXPERIENCE

Intermediaries

The FY 1982 intermediary workload increased 7.1 percent over FY 1981, whereas the total cost (excluding audit) decreased 2.2 percent. Person years for operations (excluding audit) decreased 23.4 percent in 1982 which, in view of the higher workload, resulted in a 31.3 percent increase in productivity per person year.

The unit cost for all operations decreased 43 cents, and the unit cost for operations (excluding audit) decreased 34 cents. The difference reflects an increase of 1.5 percent in audit costs.

	FY 81	FY 82	Net Change Increase (Decrease)	Percent Change Increase (Decrease)
Workload	$42,539,836	$45,551,680	$3,011,844	7.1
Total Cost	234,615,445	231,930,888	(2,684,557)	(1.1)
Provider Audit	68,425,289	69,462,781	1,037,492	(1.5)
Total Cost (Ex. Audit)	166,190,156	162,468,107	3,722,049	(2.2)
Unit Cost	$5.52	$5.09	($.43)	(7.8)
Unit Cost (Ex. Audit)	$3.91	$3.57	($.34)	(8.7)

Carriers

The unit cost decreased by 19 cents during FY 1982. This reflects a workload increase of 9.6 percent and total cost increase of 1.8 percent. Contributing to the lower unit cost was the fact that productivity increased 28.7 percent, while the personal service cost per person year increased by 12.5 percent.

	FY 81	FY 82	Net Change Increase (Decrease)	Percent Change Increase (Decrease)
Workload	169,541,671	185,769,597	16,227,926	9.6
Total Cost	$450,537,670	$458,819,529	$8,281,859	1.8
Unit Cost (Claims)	$2.66	$2.47	($.19)	(7.1)

F. PROGRAM FUNDING

Under the Social Security Act, the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund are administered by two Boards of Trustees, each comprised of the same three members who serve in an ex-officio capacity. The Secretary of the Treasury is designated by law as the managing trustee of both funds. The other members of the Board are the Secretary of Labor and the Secretary of Health and Human Services. The Administrator of the Health Care Financing Administration serves as Secretary of both Boards. The two Trust Funds were established on July 30, 1965, as separate accounts in the U.S. Treasury to hold the amounts accumulated under the respective programs. The Board of Trustees issues annual reports on the status of the two Trust funds.

The primary source of hospital insurance (Part A) financing (92 percent) is contributions, based on earnings, by workers and their employers, and by self-employed individuals. The remaining eight percent is derived from general revenues for certain insured individuals who attained age 65 before 1975, premium payments for voluntarily enrolled individuals, transfers from the Railroad Retirement Board, military service credits, Professional Standards Review Organizations, Maternal and Child Health, and interest on accumulated funds.

Supplementary medical insurance (SMI or Part B) is financed by three sources: (1) premium payments from enrollees, (2) contributions from general revenues, and (3) interest on trust fund accumulation.

When the SMI Trust Fund was initially established in 1966, the Government contribution from general revenues was equal to the premium income collected from beneficiaries under a 50=50 matching formula. Effective in 1973, under a legislative amendment, year-to-year increases in beneficiary premiums were limited to the percent by which general Social Security benefit levels had increased in the preceding year. Since July 1973, the Government contribution has increased significantly. In FY 82, the Government contributed 70.3 percent of program income and the beneficiary contribution was 26.7 percent of program income. Three percent of the income resulted from interest accumulated by the trust fund. The increase in the Government's contribution can be attributed to (1) the 1973 legislative amendment, and (2) the fact that the cost of the Part B program has increased at a rate considerably above the general cost of living adjustment applied to Social Security benefit increases. Some factors contributing to the rise in the cost of the Part B program are (1) inflation of medical prices, (2) utilization of more expensive technology in health care delivery, (3) increasing rates of utilization of services, and (4) increases in both the number of aged beneficiaries and the proportion of persons aged 75 and older within the aged population. Additionally, coverage of the disabled became effective in July 1973 at the same premium rate as for beneficiaries over 65.

More detailed information about the status of the Hospital Insurance and Supplementary Medical Insurance Trust Funds, showing income, disbursement and future projections are contained in the Annual Reports submitted to the Congress by the Boards of Trustees of the two Funds.

G. CONTRACTOR PERFORMANCE EVALUATION PROGRAM (CPEP)

In FY 82, HCFA evaluated the performance of Medicare contractors by using the Contrator Performance Evaluation Program. In this program, specified criteria are used to measure contractor Part A (hospital insurance) and Part B (medical insurance) performance in the areas of: bill processing (claims processing - Part B), utilization safeguards - Part B only, provider reimbursement (program payment - Part B), beneficiary services, fiscal administration, and general administration. These criteria are applied uniformly to all contractors within each program. Standards for unit cost of bill (claim) processing, timeliness of bill (claim) processing, timeliness of cost report settlements (Part A only), and quality of claims processing (Part B only) were also, established. The process of applying standards and criteria to intermediary performance began on October 1, 1979. Carrier performance initially became subject to the application of standards and criteria on October 1, 1980. Each subsequent year the standards and criteria are revised and refined to more accurately measure contractor performance. The CPEP is administered through HCFA's ten regional offices. Throughout the fiscal year, the regional staffs evaluate contractor performance by conducting onsite reviews and analyzing performance data. At the end of the year, Annual Contractor Evaluation Reports (ACERs) are prepared citing CPEP results and are published by the regions for each contractor in their service area.

HCFA uses the results of the application of CPEP criteria and standards to the contractors' performance to identify the contractors having deficient performance. When combined with historical perspective, this process has proven to be an effective tool for identifying those contractors exhibiting a pattern of continuing poor performance with little or no apparent improvement. Establishment of performance goals and monitoring systems, and the practice of conducting face-to-face meetings between senior HCFA staff and executives of poor performing contractors, have achieved overall improvements in contractor operations.

In developing the FY 82 revision, HCFA has taken under consideration budget limitations and has reduced the scope of the CPEP process in an effort to simplify the review process and conserve both contractor and regional resources. In spite of this, there was increased emphasis placed on evaluating output measures instead of process. Due to the budget situation, we focused on payment safeguards which would provide a greater savings in program dollars. This was accomplished by refining our standards to prevent overpayments by tightening provider reimbursement ranges for measuring the variance between interim payments and reimburseable cost. We also took stronger measures to recover overpayments.

The program integrity performance levels for intermediaries (Part A) seek to ensure that:

1. desk reviews of provider cost reports are performed to verify that providers are receiving appropriate program reimbursement;

2. full-scale in-depth audits are performed when appropriate;

3. improper or nonallowable costs are identified and necessary adjustments are made;

4. instances of potential fraud and abuse are identified and referred for investigation; and

5. sanction action (exclusion or termination from participation in the program) is taken when appropriate.

The program integrity performance levels for carriers (Part B) seek to ensure that carriers:

1. monitor the Medicare claims experience for all individual and group physician/suppliers, and acquire statistical data on them and their specialty groups;

2. identify and review those physicians by locality and specialty whose utilization patterns differ from medically recognized standards, criteria and norms;

3. correct any program abuse or overutilization of provider service by recovery of overpayments;

4. prevent further abuse in the utilization of services by educating physicians/suppliers in the acceptable norms of practice;

5. identify those individual providers or types of services where prepayment controls are necessary;

6. refer cases for sanction action (exclusion from participation in the Medicare program) if corrective action has been unsuccessful; and

7. properly handle and refer for investigation, fraud and abuse complaints received from beneficiaries, interested parties, or other sources.

CHAPTER II. PROGRAM ADMINISTRATION

A. SUMMARY OF ADMINISTRATIVE STRUCTURE

The overall responsibility for administration of Medicare is vested by law in the Secretary of Health and Human Services. The statute also provides for significant participation in certain areas of administration by private organizations and public agencies.

Within the Department of Health and Human Services, primary responsibility for administering the Medicare program is assigned to the Health Care Financing Administration (HCFA). Special responsibilities in connection with health care standards of Medicare have been assigned to the Public Health Service. The Office of Civil Rights of the Department is responsible for assuring necessary conformance by participating health care facilities with Title VI of the Civil Rights Act of 1964.

Role of the Health Care Financing Administration - The Health Care Financing Administration negotiates and administers agreements with (1) the intermediaries and carriers which perform payment and other program functions, (2) the State agencies which certify health facilities for participation in the program, and (3) hospitals and other institutions which provide services for which the program makes reimbursement. HCFA enrolls Medicare beneficiaries and ensures that a Medicare card is mailed to each entitled beneficiary. It bills and collects premiums from direct-paying beneficiaries and third party payors. It maintains computerized master records which provide current information about beneficiary eligibility, deductible status, and utilization. HCFA also develops reimbursement principles and guidelines, participates with the Public Health Service in the formulation of the conditions of participation, formulates Medicare regulations, develops program policy and procedural instructions, and performs the basic recordkeeping and data processing functions required for administration of the program. It determines and reconciles payment liability of group health plans. Additionally, HCFA assures the quality, appropriateness and necessity of services for program beneficiaries.

Role of the Social Security Administration (SSA) - With the establishment of HCFA on March 8, 1977, responsibility for Medicare activities was transferred from SSA. However, by agreement, SSA continues to perform some functions. Chief among these are: (1) District Office Services - Applicants for Medicare continue to make applications for Medicare coverage, as well as make inquiries and file appeals, to SSA District Offices. SSA District Office staff also respond to inquiries regarding Medicare, process beneficiary appeals, explain Medicare eligibility requirements, make eligibility determinations, obtain required proofs, and issue notice of Medicare eligibility; (2) Computer Support - SSA provides computer resources and operational personnel to process HCFA programs; (3) Appeals Function - Certain appeals functions are handled by SSA. These include beneficiary appeals (Part A) where more than a statutory minimum is at issue.

Role of the Public Health Service - The Department's Public Health Service (PHS) acts as a valuable resource in the professional health aspects of the Medicare program. PHS participates with the Health Care Financing Administration in formulating the conditions of participation for providers of services, provides assistance to the State agencies in carrying out their Medicare responsibilities, supports and evaluates experimental approaches to utilization review, and provides professional advice on many technical and medical aspects of program administration.

During FY 82, HCFA referred 45 new coverage issues to the PHS, and published 15 instructions based on advice received from the PHS. An additional number of coverage issues were resolved adequately without the need for published instructions.

Role of the Public Health Service - The Department's Public Health Service (PHS) acts as a valuable resource in the professional health aspects of the Medicare program. PHS participates with the Health Care Financing Administration in formulating the conditions of participation for providers of services, provides assistance to the State agencies in carrying out their Medicare responsibilities, supports and evaluates experimental approaches to utilization review, and provides professional advice on many technical and medical aspects of program administration.

During FY 82, HCFA referred 45 new coverage issues to the PHS, and published 15 instructions based on advice received from the PHS. An additional number of coverage issues were resolved adequately without the need for published instructions.

Role of the Office for Civil Rights - Title VI of the Civil Rights Act of 1964 provides that no institution, agency, or activity receiving Federal financial assistance may engage in discriminatory practice on the basis of race, color, or national origin. Thus, before any hospital, skilled nursing facility or home health agency may be a participating provider under Medicare, its compliance with the provisions of Title VI must be assured. The Office for Civil Rights is responsible for assuring compliance with Title VI.

Role of the State Agencies - The law requires that, wherever possible, the Secretary uses the services of appropriate State or local health agencies or other appropriate State or local agencies in determining whether providers of services and independent laboratories meet the conditions for participation in the Medicare program. All 55 jurisdictions (including the District of Columbia, Puerto Rico, the Virgin Islands, Guam, and American Samoa) have designated agencies -- in most instances State health agencies -- to perform this function.

In carrying out their responsibilities under the health insurance program, the State agencies conduct field surveys of institutions and agencies to determine the extent to which these facilities meet the applicable conditions of participation. They also undertake periodic resurveys of participating facilities to determine whether they continue to meet such conditions and provide consultative services to facilities experiencing difficulties in meeting the participation requirements. The agencies identify non-participating hospitals which can be reimbursed under the program for emergency services, and coordinate activities under the health insurance program with activities conducted under medical assistance programs. The State agencies are reimbursed for the costs of activities they perform in the program, including related costs of administrative overhead and staff.

Role of the Intermediaries - Participating hospitals, skilled nursing facilities, and home health agencies may either receive program reimbursement through a fiscal intermediary or receive payment directly from the Government. Most providers have chosen to deal through intermediaries. Under agreements with the Secretary of Health and Human Services, the intermediary is responsible for determining whether services are covered, the reasonable costs of services provided to beneficiaries, and for reimbursing providers for these costs on behalf of the program. In addition, the agreements authorize the intermediary to provide consultative services to providers, to make audits of provider records, and perform related functions. All agreements also require that the intermediary must assist providers in establishing and applying safeguards against the unnecessary use of services covered under the program. As of September 30, 1981, there were nine insurers operating as fiscal intermediaries on behalf of over 14,000 participating providers. The insurers include the Blue Cross Association (with subcontracts to 58 Blue Cross plans) and 8 commercial insurers (Appendix A). Submitting bills directly to HCFA were: 222 hospitals, 56 skilled nursing facilities, 428 home health agencies, 20 outpatient physical therapy providers, 150 comprehensive health centers, 377 Federal hospitals, 6 emergency hospitals, 35 hospitals providing services to migrant farm workers and 6 free-standing end-stage renal disease dialysis facilities. In addition to this regular intermediary workload, HCFA serviced 1,600 other providers involved in program demonstration projects. HCFA also provided accounting and reimbursement services (but not claims processing services) for 34 Kaiser-Permanente facilities nationally.

Role of the Carriers - To make program payments under the medical insurance program, the Secretary is authorized to enter into contracts with organizations already engaged in providing, paying for, or reimbursing the cost of health services under group insurance policies or similar group arrangements in return for premiums or other periodic charges. Applying Federal statutes, regulations and instructions, the selected carriers determine whether services are covered and the amounts to pay physicians and suppliers for services rendered under the program and make payments for such services on behalf of the program. Under the terms of their contracts with the Secretary, they are required to assist in the application of safeguards against the unnecessary utilization of services, and to serve as a channel of communication for information relating to the administration of the program.

As of September 30, 1981, there were 25 Blue Shield plans, 13 insurance companies, 1 data processing company, and 1 State agency operating as carriers (Appendix B).

B. ACHIEVING MORE EFFICIENT INTERMEDIARY AND CARRIER PERFORMANCE

Essentially, beneficiaries and the health community, as well as the public at large, judge the performance of Medicare by the performance of intermediaries and carriers. Contractors' effectiveness in processing claims, in communicating program policies and procedures to the public and in establishing relationships with the health community, shapes the public and professional response to the program.

Within general guidelines issued by the Health Care Financing Administration, the intermediaries and carriers must develop effective administrative mechanisms for achieving required program results. This has led to different patterns in the internal administration and operation of the intermediaries and carriers. Much of the success of Medicare, particularly its acceptance by the health community, is attributable to the opportunities presented by such an administrative pattern. Intermediaries and carriers can develop uniquely responsive mechanisms to meet the variable patterns in the nation's health care system.

Description of Intermediary Claims Process

Basically the Part A intermediary claims process involves (1) determining the amount of program reimbursement due to providers for covered services furnished Medicare beneficiaries and (2) making periodic payment of those amounts to providers. In the intermediary claims process the provider, rather than the beneficiary, submits the claims. Each claim is a bill of record of services rendered which is accumulated with all other such records from that provider until the end of its accounting period. At that time a final cost settlement is made for all covered services rendered by the provider in that accounting period.

The intermediary claims process for Part A hospital insurance claims is summarized as follows: When a Medicare beneficiary is admitted to a participating hospital or skilled nursing facility, or begins a course of treatment based on a plan of care from a home health agency, the provider sends the intermediary an admission or a start-of-care notice. The intermediary queries the Health Care Financing Administration's central record system for the patient's entitlement and deductible status, and remaining eligibility for benefits. The intermediary then advises the provider of the patient's eligibility for further benefits and his deductible status. Admission and start-of-care notices are sent to the Health Care Financing Administration by teletype or magnetic tape, or by direct magnetic tape to magnetic tape transmission over high-speed wires. Replies are usually sent to the intermediary on the second working day after a request for eligibility information has been made.

During the course of treatment, or after beneficiaries are discharged from the hospital or skilled nursing facility or complete a course of home health treatments, the provider submits claims to the intermediary. These claims are used to determine the level of interim payment due the provider, subject to final settlement at the end of the accounting period. Utilization data are forwarded to the Health Care Financing Administration to update the central records. Consequently, accurate information can be provided when replying to subsequent notices of admission or starts of home health care. As part of the updating process, Explanation of Medicare Benefit notices are sent to the beneficiaries to inform them of (1) services for which the program paid, and (2) the inpatient days or home health visits used in the current benefit period.

Description of Carrier Claims Process - Carriers reimburse reasonable charges on all claims for physicians' services and other covered medical services that are reimbursable on a charge basis. These claims may or may not be accompanied by copies of physicians' or suppliers' bills. If beneficiaries complete the claim form, they attach bills received. Bills are not attached if the claim is completed by a physician or supplier under assignment, or as an assistance to the claimant. Every claim received by the carrier requires two determinations in respect to each distinct service furnished the beneficiary. First, a determination must be made as to whether the service is covered. If the service is covered, a determination must be made as to the reasonable charge for that service. The efficiency of the carrier claims process is, therefore, greatly dependent upon securing detailed itemization of services rendered. Additionally, carriers must maintain accurate and current information concerning independent physician and supplier charge patterns for similar services to other patients in the same locality.

The basic steps in the carrier claims process are briefly summarized as follows: Upon receipt of claims, controls are established to assure proper disposition and to permit location of claims in the event of inquiry. Claims are reviewed for coverage of services and for completeness of information. They are then forwarded for determination of reasonable charges. The bill charges are compared with the customary charges of the physician for such services, and with the prevailing charge established in the locality for similar services. Increasingly, this comparison is accomplished through a computer process in order to handle the volume of claims expeditiously and economically.

It should be noted that each carrier receives claims for payment of medical insurance benefits provided by physicians or suppliers located within its geographic area. This continuity of relationship between the carrier and the physicians and supplies in a geographical area is essential for the establishment and maintenance of customary and prevailing charge data.

As in the hospital insurance program, HCFA maintains a master eligibility and utilization record of all medical insurance enrollees. As an important step in the claims process, carriers must determine current claimant eligibility for benefits and whether the claimant has met the current year deductible. If the carrier has processed claims earlier in the year, its history file may have information regarding the status of the deductible. If not, the carrier queries the HCFA master record by transmitting essential identifying information and the amount of the reasonable charge. The same transmittal facilities available for intermediaries in Part A are used. HCFA, in updating the master record, responds to the query, generally within 24 hours. HCFA verifies eligibility and identifies the amount of the deductible remaining to be satisfied. The carrier then makes the appropriate payment to the physician or supplier if an assignment has been taken or, if not, to the beneficiary. In assignment cases, the explanation is sent to the physician or supplier with a copy to the beneficiary.

Improved Desk Review Process for Fiscal Intermediaries

The desk review process is used by fiscal intermediaries to decide which provider cost reports to audit and to determine the scope of that audit. HCFA developed in FY '82 new procedures for use by fiscal intermediaries that reduced the average time for desk review from 40 hours per cost report to 15 hours per cost report.

Cost Report Evaluation Program (CREP)

CREP is designed to evaluate the quality of the settlement of Medicare hospital and home health agency (HHA) cost reports. CREP reviews are conducted on an annual cycle from October-September of each year. These reviews were the basis for designing corrective action strategies for errors in cost settlements; identifying and recouping overpayments; identifying areas in the regulation, instructions, and policies which require revision or clarifications; issuing an annual analysis report; and assessing regional offices in performance of administering the program.

Carrier Quality Assurance Program

The Health Care Financing Administration also maintains a formal carrier quality assurance program. The primary purpose of the program is to provide a statistically valid and objective procedure for evaluating Part B contractors' performances in the quality of claims processing.

Contracting Initiatives and Experiments

Under Section 222 of P.L. 92-603, HCFA was granted experimental authority to test incentive contracting for intermediary and carrier administrative functions. Under an incentive contract, intermediaries and carriers are reimbursed on other than a cost related basis, rather than on actual costs incurred. They are at risk and may suffer monetary damages for failure to meet performance objectives. As a result of assuming the risk of nonperformance, the intermediary's or carrier's internal management is responsible for improved efficiency and economy in operations. HCFA has taken action in the experimental contracts to assure that a continuing high level of service to Medicare beneficiaries and providers is maintained. In each experimental contract, performance requirements have been introduced which exceed those applied to the incumbent contractors reimbursed on a cost basis.

The use of incentive contracts on an experimental basis, authorized by Congress in 1972, is a departure from the basis statutory authority directing HCFA to reimburse contractors for the necessary and proper cost of administration of their contract duties. The experimental contract utilize selected performance standards and existing quality control and performance review procedures and provide for the assessment of liquidated damages if the contractor fails to meet the standards established. Evaluations are made of actual performance against the standards. They are completed on a quarterly basis by regional office staff.

By FY 78, four experimental contracts were awarded. They involved the Maryland, Maine, Illinois, and upstate New York carrier service areas. The first was an annual prospectively negotiated fixed rate experiment with an incumbent carrier. The second, third, and fourth were competitively bid fixed-priced contracts for Part B carrier geographic areas. The experimental contracts are being evaluated to determine the advantage and disadvantage of these forms of contracts. Although the evaluations are not complete, some preliminary observations have been made. The process of selection and subsequent negotiations of these experimental contracts has demonstrated the willingness of the Blue Cross Plans, the Blue Shield Plans and commerical insurance companies to operate in an incentive/risk environment and use specific standards to measure performance which may result in monetary damages being assessed for poor performance.

The Maryland Blue Shield contract was the first incentive-type reimbursement contract between HCFA and one of its Part B contractors. This experimental contract was an annual prospectively negotiated fixed rate experiment. This prospective fixed rate contractual agreement with Maryland Blue Shield followed a general solicitation to all Part B Medicare carriers for participation in a fixed rate experiment. Nineteen carriers responded to the general solicitation. The experimental fixed rate contract with Maryland Blue Shield was for a two-year period (calendar years 1977 and 1978). In the experiment, Maryland Blue Shield realized net earnings in the first year of $274,161, which included a reduction in payments for failure to satisfy one of the performance requirements in the agreement. The second operational year (calendar 1978) of the contract had a negotiated fixed rate 8.1 percent below that which was negotiated in the first year of the contract. During 1978, the contractor sustained a net loss of $74,597, thus realizing a net gain over actual incurred costs of $199,564, or 2.64 percent, for the two years. As of January 1, 1979, Maryland Blue Shield reverted to a cost contract in accordance with the option contained in the experimental contract.

In 1977, the Union Mutual Life Insurance Company in Maine decided not to review its Medicare Part B carrier contract but rather, to concentrate its efforts and resources on private business. This decision and the relatively small claims volume for Maine presented an ideal opportunity to test the competitive fixed-price concept in Medicare under the experimental provisions of Section 222 of P.L. 92-603. Through competitive selection, Blue Shield of Massachusetts (BSM) was chosen to replace Union Mutual. BSM contracted with HCFA to process Part B medical insurance claims for fixed-price from December 1977 through September 1980. The contract held BSM to performance standards, including provisions for liquidated damages in the event of substandard performance.

During FY 1979, HCFA and BSM successfully negotiated a 1-year extension to the existing contract to process the Maine Part B workload for a price of $2,190,227. On February 6, 1981, HCFA recompeted the Maine Part B contract. Announcement of award occurred on June 1, 1981. The successful offeror was again BSM. The term of the contract was October 1, 1981 - September 30, 1984.

A HCFA experimental fixed-price contract in Illinois is intended to test the effect of merging carrier service areas and the cost benefit effects of price competition in a medium claims volume service area. The service areas involved are Cook County, formerly serviced by the Health Care Service Corporation (HCSC), and the remainder of the State of Illinois, formerly serviced by Continental Casualty (CNA). The operational period of the fixed-price contract is April 1979 to September 1983. The successful offeror for this contract was Electronic Data Systems Federal Corporation (EDSF), an organization that had not been a carrier in the Medicare program but had extensive experience in Medicare data processing. The projected savings to be realized by this experimental contract are $34,790,200. Some major operational difficulties were experienced during the first year for which liquidated damages were aseeassable ($2,037,750 in liquidated damages were assessed through September 30, 1981); however, the contractor has made significant progress in overcoming those difficulties.

In New York, HCFA selected a Part B carrier for the upstate New York area through a competitive process. The experimental contract was intended to test the cost benefit effect and operating efficiencies of merging three carrier service areas in the aggregate medium claims volume service are. The area was previously serviced by Blue Shield of Western New York, Genesee Valley Medical Care, Inc., and Metropolitan Life Insurance Company. The successful offeror for this contract was an incumbent carrier, Blue Shield of Western New York (BSWNY). The operational period of this contract was June 1979 to September 1982. The savings realized for this contract were $15,496,000. Liquidated damages were assessed against this contract in the amount of $110,816.97 for performance deficiencies in the period January through June 1980.

The performance difficulties encountered at the beginning of the contract period were corrected, and by the time the contract expired in September 1982, the carrier was among the best performing carriers nationally. Since October 1982, BSWNWY has been operating under a cost reimbursement contract with a negotiated ceiling on costs, above which the government will not be responsible.

In FY 80, HCFA negotiated a Part A fixed-price incentive contract with the Blue Cross Association (BCA) and Blue Cross/Blue Shield (BC/BS) of Greater New York (Plan) to consolidate all the Blue Cross Plans in the State of New York. This procurement resulted from an unsolicited proposal submitted by Blue Cross Association and the Plan. Under the contractual arrangement, BCA is the intermediary and Blue Cross and Blue Shield of Greater New York serves as the subcontractor and handles the operational aspects of the arrangement. The outgoing Plans continue to be involved under purchase service agreements beneficiary and provider services in their localities. The contract, which became operational during FY 81, reduced the number of subcontractors (Blue Cross Plans) within the State from seven to one. The outgoing Blue Cross Plans terminated their operations on a staggered schedule and the central site in Syracuse assumed the entire operaton May 1, 1981. The contract extends through April 30, 1984, and provides incentives for excellent performance as well as for the imposition of liquidated damages for less than satisfactory performance. The new subcontractor will process an estimated 12.8 million bills during the term of the contract. The total amount of the operational phase of the contract is $48,903,000.

The first fixed-price competitive bid contract under Part A was to have been awarded for the State of Missouri on July 2, 1979. The term of the contract was to have been January 1, 1980, through December 31, 1982. Court action was initiated against DHHS and on June 29, 1979, the U.S. District Court for the Western District of Missouri rendered a decision which enjoined DHHS from making an award in the procurement. Among other things, the parties initiating the suit contended that the planned experiment violated existing Medicare legislation, which permits participating providers of health care services to nominate their Part A fiscal intermediary. On August 27, 1979, DHHS filed an appeal with the U.S. Court of Appeals for the Eight Circuit requesting a reversal of the lower court's decision. On June 9, 1980, favorable decisions for the Government were rendered by the Appeals Court in Missouri and subsequently by the District Court after additional litigation. Thereafter, on September 19, 1980, HCFA proceeded with the experiment by updating the Request for Procurement (RFP) and seeking "Best and Final" offers from those organizations which had responded to the original RFP. Following an evaluation of these "Best and Final" offers, HCFA announced on November 19, 1980, that a contract would be entered into with Blue Cross of St. Louis. The new contract period is from November 10, 1980, through November 30, 1984 and contains provisions for the assessment of liquidated damages in the event of poor performance. The total cost of the contract is $13,791,100, with a projected savings of $2 million.

For an experiment to test the potential efficiencies of merging several contractor operations in a multi-State environment and the feasibility of a common claims process for the Medicare Parts A and B programs, an RFP in the Colorado, Utah, and Wyoming service area was released on August 2, 1979. A preproposal conference on the RFP was held on September 12, 1979. On September 14, 1979, the Blue Cross Association, along with Blue Cross/Blue Shield of Colorado, Blue Cross/Blue Shield of Wyoming and Blue Shield of Utah, filed a suit with the U.S. District Court for the Western District of Wyoming requesting that the DHHS be enjoined from conducting this experiment. The issues in the litigation are similar to those in the Missouri litigation.

On November 1, 1979, the Court enjoined DHHS from awarding a contract under this proposed experiment. On December 31, 1979, DHHS filed an appeal with the U.S. Court of Appeals for the 10th Circuit. The final brief was submitted by DHHS on August 22, 1980. (In a decision rendered November 19, 1981, DHHS (HCFA) won all points.)

While HCFA received a favorable decision from the United States Appellate Court the elapsed time between the receipt of the proposals and the date of the Appellate Court's decision invalidated prior proposals. It was, therefore, necessary for HCFA to reassess the practicability of the planned multi-State experiment. After considering the issues involved, HCFA issued a new RFP for a competitive fixed-price contract with provisions for incentive payments and assessment of liquidated damages. The procurement would be a combined Part A and B experiment for the State of Colorado only.

The RFP to select a single contractor to administer the combined Medicare Part A and Part B programs for the State of Colorado was issued on August 9, 1982.

We received only one proposal. The single offer was one of the incumbent contractors, Blue Cross and Blue Shield of Colorado (BCBSC). Electronic Data Systems Federal (EDSF) was named as subcontractor in the BCBSC proposal. In addition to the primary proposal, BCBSC submitted an alternative proposal, which became the winning bid. Announcement of award occurred on December 10, 1982. Under the alternative proposal, BCBSC proposed that the existing Part A Processing operation system be continued in operation until June 30, 1983. Total costs for the contract is $31,899,866 with a projected savings of $4,088,934.

As part of HCFA's plan to improve service to beneficiaries and providers, and to reduce the number of contractors in the Medicare program, three contract initiatives were undertaken. The first involved consolidation of the Part A workload in the State of Tennessee. This consolidation made the Chattanooga Blue Cross Plan the sole Part A subcontractor for the State, beginning April 1, 1981. However, part of the arrangement provides for the Memphis Blue Cross Plan to continue performing some Part A functions under subcontract with Chattannoga Blue Cross.

In a similar arrangement, Pennsylvania Blue Shield became the Part B carrier for the State of Delaware, replacing Delaware Blue Shield. Delaware Blue Shield continues to perform some carrier functions under subcontract with Pennsylvania Blue Shield.

Pennsylvania Blue Shield also was awarded full responsibility for Part B carrier functions in the Washington, D.C., metropolitan area, effective October 1, 1981. Previously, Medical Services of D.C. was the carrier for this area.

Other FY 82 Ongoing Performance Improvement Initiatives:

1. Intermediary Systems Testing Project (ISTP)

   ISTP is a mechanism designed to evaluate the performance of Part A claims processing systems. It is a tool used to detect contractor systems deficiencies and claims processing weaknesses. The test simulates live processing by providing the contractor with a package of 133 sample claims (bills) covering a wide range of bill processing situations and error conditions. The sample claims are to be processed from the initial query stage to final bill disposition. ISTP contains bills which are used to test the intermediary's ability to make correct entitlement, eligibility, and utilization determinations. The sample bills are processed from the initial query stage to final bill disposition, thus encompassing the following major areas of Part A claims processing:

   a. Query/Query reply

   b. Payment calculation

   c. Notices sent to beneficiary and provider

   d. Payment preparation and disbursement

   In FY 1982, tests were conducted at 34 intermediary sites.

2. Carrier Systems Testing Project (CSTP)

   CSTP is a mechanism designed to evaluate the performance of Part B claims processing systems. It is a tool used to detect contractor systems deficiencies and claims processing weaknesses. The test simulates live processing by providing the contractor with a package of 167 sample claims covering a wide range of claims processing situations and error conditions. The sample claims are to be processed beginning with their clerical input to the final disposition of the Explanation of Medicare Benefits (EOMB).

   CSTP reviews major areas of Part B claims processing such as:

   a. Query/Query reply

   b. Payment calculation

   c. Notices sent to beneficiary

   d. Payment preparation and disbursement

   In FY 1982, tests were conducted at 26 carrier sites.

3. Electronic Media Claims (EMC)

HCFA's efforts to increase the volume of electronic media claims (EMC) submitted by Medicare providers to contractors (intermediaries and carriers) has increased significantly during 1982. The greatest increases occured in the fourth quarter, due primarily to the establishment of national and regional EMC goals in July. Individual EMC goals were established for each contractor as a percentage of their total claims volume receipts that they were expected to receive electronically. The national averages for EMC receipts for FY 1982 were 17 percent for Part A and 8 percent for Part B. We anticipate continuing upward trends in the levels of Part A and Part B automated billing during FY 1983.

4. Provider Uniform Billing

On March 26, 1982, the Secretary and the Administrator jointly announced plans to implement a uniform institutional provider billing form for Medicare and Medicaid. The form chosen was developed under the auspices of the American Hospital Association and known as UB-82. This form is a successor to earlier uniform bills that were tested in a number of States. Substantial savings for providers and third-party payors are projected from implementation of a single billing form acceptable to all major payors. Uniformity in the bill data set is also expected to accelerate movement to electronic techniques.

5. Carrier Alphabetic Stat

The CAST is an alphabetic listing of all Medicare beneficiaries residing in a geographic locale. It includes basic identification data for each beneficiary: Medicare claim number, complete name and address, sex, and date of birth. A CAST listing is created for each State, the District of Columbia, Puerto Rico, Guam, Virgin Islands and American Samoa. Updated listings are produced and distributed every six months (spring and fall) to HCFA regional offices, carriers, intermediaries, State buy-in agencies, and the Railroad Retirement Board regional offices.

The purpose of CAST is to assist Medicare claims processing contractors and HCFA regional offices in resolving beneficiary identification problems encountered when processing Medicare bills and claims and in maintaining State buy-in rolls. It substantially reduces the referral of large numbers of such problems to the SSA district offices.

The use of the conversion of CAST from microfilm to microfiche listings during FY 81 and a commerical micrographic service bureau to produce the microfiche listings has resulted in a significant reduction of the CAST annual production cost and in more timely CAST data being provided to carriers and intermediaries.

6. Beneficiary Toll Free Telephone Service

During FY 81, the Part B carriers received approximately 4.2 million beneficiary inquiries on toll free lines at an approximate cost of $2.33 per call or $.06 per claim processed. Total administrative cost to the program was $10.0 million. Toll free service is generally perceived by the public as a valuable and tangible indication of the contractors' responsiveness to beneficiary concerns. It also encourages the public to call the contractor about Medicare questions rather than the Social Security district offices. However, budget reductions for administrative costs during FY 82 caused some diminution in the availability of this service and an increase in the likelihood of busy signals.

C. REIMBURSEMENT CONTROLS/POLICY INITIATIVES

The Medicare program presently has two components established by Title XVIII of the Social Security Act. Hospital Insurance (Part A) provides for payment of inpatient services furnished by hospitals and other institutional providers of services on a "reasonable cost" basis. Supplementary Medical Insurance (Part B) provides for reasonable cost reimbursement of outpatient institutional services and payment or services furnished by physicians and other suppliers on a "reasonable charge" basis.

To implement these reimbursement principles, it is essential that the Medicare program establish tests of "reasonableness" to ensure the continued delivery of high quality health services to beneficiaries and assure that unwarranted costs and charges are not paid. In FY 81, several reimbursement policy initiatives were undertaken to continue to meet these objectives.

Reasonable Cost Reimbursement Initiatives

Background - Under the original Act, provider reimbursement of reasonable costs included all necessary and proper expenses incurred in the delivery of patient care. It was soon recognized, however, that reimbursement on the basis of incurred costs did not offer sufficient incentives to control the rapid escalation of health care expenditures. The enactment of P.L. 92-603, the Social Security Amendments of 1972, greatly enhanced HCFA's ability to control Medicare costs.

Section 223 of P.L. 92-603 amended the definition of reasonable cost in Section 1861(v)(1) of the Social Security Act to exclude costs determined to be unnecessary in the efficient delivery of needed health services. Congress reasoned that health care institutions, like other enterprises, should face the financial consequences of inefficiency. The Amendments authorized the establishment of prospective limits so that providers could act to control their costs. It was felt that the establishment of prospective limits would reduce provider financial uncertainty by defining limits prior to the onset of the cost reporting period to which they applied.

Regulations implementing Section 223 authorized the establishment of prospective cost limits based on provider classification according to such factors as similarity in size, location, and economic characteristics. The regulations also established the conditions under which providers may be entitled to a change in classification, an exemption from, or an exception to the limits. The statute and regulations also provided for relief by allowing a provider, under certain cirmcumstances, to charge excess costs to the beneficiary.

In granting the authority to establish prospective ceilings on costs, Congress was aware of the difficulties that could arise due to deficiencies in cost data, or because of limitations in measuring health care output and defining efficient delivery of care. Congress in the past recognized that the initial limits would, of necessity, be imprecise and affect a relatively small number of providers. The expectation, however, was that cost limits would be established to the extent currently feasible with continuing refinement as appropriate methodology developed. Consistent with this expectation, in FY 80 HCFA modified the 223 limit setting methodology for hospitals and home health agencies and extended its application to skilled nursing facilities.

Although the methods for establishing the 223 limits vary by provider type, they had several common features. The limits were derived from reported costs of comparable facilities. Cost data were obtained from Medicare fiscal intermediaries. Comparability was achieved by provider classification according to predetermined criteria. The criteria was uniformly applied so that the basis for classification is identical for each facility. The result was a classification system which produced reasonably homogeneous groups so that costs from similar providers could be compared. For each group, costs beyond a certain statistical threshold were presumed (in the absence of evidence to the contrary) to be greater than the costs necessary to deliver health services efficiently. The cost limits, therefore, restricted the recognition of "reasonable cost" to a standard cost representative of that experienced by similar providers. HCFA directed most of the FY 80 changes in the limit setting methodology toward improving the homogeneity of the classification groups to enhance the equity of the limits as a presumptive measure of efficiency.

On August 13, 1981 the Congress passed the Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35) which, for the first time, defined in the statute the level at which the cost limits would be set. These levels were 108 percent of the classification group mean for hospitals and at the 75th percentile of the home health agency classification groups. The reduced levels of limits were to become effective for services provided on or after October 1, 1981. Notices implementing these changes were published in the Federal Register on September 30, 1981.

Section 2142 of P.L. 97-35, as defined in the statute, directed the Secretary to establish limitations on the reasonable cost of and reasonable charge for outpatient services. The limitations were established to the extent feasible and were reasonably related to charges for similar services in physicians' offices in the same area. HCFA initiated the development of methodology for setting these limits.

Treatment of Cost of Uncompensated Services Furnished in Fulfillment of a Hill-Burton Free Care obligation - Under the Hill-Burton legislation amending the Public Health Service Act, medical care facilities applying for grants, loans, and loan subsidies are required to assure that they will make available "a reasonable volume of uncompensated services to persons unable to pay" for them. Under program rules each facility that received Hill-Burton financing is obligated to furnish annually, for a twenty-year period, a certain volume of uncompensated services. In accordance with section 106 of TEFRA, during FY 82, HCFA developed a regulation to state explicity that, with certain exceptions, Medicare will not share in the costs of uncompensated services furnished by a provider in fulfillment of a Hill-Burton free care obligation. This regulation was issued on October 1, 1982.

REIMBURSEMENT FOR HOSPICE CARE -- Section 122 of the Tax Equity and Fiscal Responsibility Act authorized coverage for hospice care services effective November 1983. Hospices provide care to terminally ill individuals. The final regulations implementing this provision outline eligibility requirements, establish conditions of participations, define covered services and implement a prospective payment system for hospice care. With the exception of payment for physician services, the prospective payment system provides reimbursement at one of four predetermined rates for each day of hospice care, depending on the level of care furnished to the individual. Physician services will be reimbursed separately on a fee-for service basis. The Medicare hospice benefit is a Part A benefit, and will end on September 30, 1986, under current legislation.

1. Reasonable Cost Limits - Hospitals - Pending the development of a classification system sophisticated enough to quantify such difficult to measure variables as case-mix and scope of service, HCFA placed limits on hospital general routine service costs. Routine costs are basically the costs of room, board, and general nursing services and exclude any costs associated with ancillary services and special care units, such as intensive or coronary care. HCFA published schedules of limits on hospital inpatient routine service costs annually since 1974.

   In developing the initial schedule of limits, HCFA classified hospitals using only two variables - bed size and economic environment. The latter was reflected by geographic location (urban or rural) and area per capita income level. Because this method was relatively unsophisticated, the limits were established at a high level (the 90th percentile plus ten percent of the median per diem cost) permitting a wide margin for any variables not recognized by the system. Previous refinements have been incorporated in the limit setting methodology, permitting a lowering of the level of the limits. However, the basic system of hospital classification remained essentially unchanged until 1979.

   The methodology was substantially revised for the hospital limits effective July 1, 1979. Costs not reflective of relative efficiency of operation, such as capital, malpractice insurance, and medical education expenses, were excluded in deriving and applying the limits. All urban hospitals were then classified into four bed size groups without any distinction for economic environment. Rural hospitals were categorized into three bed size groups in the same way. The portion of cost attributable to wages was adjusted for differences in area wage levels by an index developed from hospital wages paid within the locale. Hospital costs were previously adjusted for inflation using a "market basket" of goods and services hospitals typically purchased in furnishing routine care. Prior to adoption of the technique, inflation adjustments were based on actuarial estimates of cost increases. Additionally, HCFA included an adjustment to increase the limits for hospitals located in States furnishing less than the national average days of care per 1,000 Medicare beneficiaries.

For the limits effective July 1, 1980, HCFA retained the basic features of the FY 1979 limits. However, a further adjustment was provided to account for additional costs which result from teaching programs but not specifically identified as teaching costs. Also, the proportion of costs subject to adjustment by the wage index was increased to approximate the actual economic environment. Because these improvements enhanced cost homogeneity, the level of the limits was set at 112 percent of the group mean. A mean based threshold avoided the objection to the percentile based limits under which a certain percentage of hospitals in each group was judged inefficient even where actual cost variations were minor.

The limits effective July 1, 1981, retained the same methodology used in FY 1980.

Purchased Management and Administrative Support Services

Under Medicare principles of reimbursement in 42 CFR 405.421, providers of services may not be reimbursed for unreasonable costs. Reasonable costs are limited to necessary and proper costs prudently incurred by a provider in furnishing services under title XVIII and related to the care of beneficiaries. As a result of questions regarding the reasonable cost of management and administrative support services purchased by providers, HCFA issued manual instructions in March 1982 which provide guidelines for applying the principle of reasonable cost to the cost of these purchased services. The instructions were issued to assist both providers and intermediaries; intermediaries may also use whatever additional techniques and analysis are necessary to assure the costs reimbursed are reasonable.

Reimbursement for Assistants at Surgery (Section 113)

The provision prohibits reasonable charge reimbursement for an assistant at surgery in hospitals where an approved training program exists in the specialty and a qualified staff physician is available to provide the service, except when: (1) the surgery is performed by a team of physicians needed to perform complex medical procedures; (2) the patient has multiple conditions which require the presence of, and active care by, a physician of another specialty during surgery; and (3) exceptional medical circumstances exist. Interim final regulations implementing this provision were issued October 1, 1982.

Elimination of Medicare Indirect Subsidy for Private Rooms

Section 111 of P.L. 97-248 specifies that the Secretary shall not allow as a reasonable cost the estimated amount by which costs for nonmedically necessary private rooms used by Medicare beneficiaries exceeds the costs which would have been incurred for semi-private accommodations. On September 28, 1982, HCFA published an interim final rule implementing section 111 for cost reporting periods beginning on or after October 1, 1982. Prior to this change in policy, Medicare had been sharing in the cost of nonmedically necessary private rooms for Medicare beneficiaries based on reimbursement for inpatient general routine services on an average cost per diem, including the costs and days of private room accommodations.

Revision of Hospital and Skilled Nursing Facility Cost Reports

HCFA issued revised cost reporting forms for hospitals and skilled nursing facilities to implement various provisions of the Omnibus Reconciliation Act of 1980 (P.L. 96-499) to incorporate into the cost report settlement the retroactive adjustment of provider-based physician payments where charges are based on physicians' compensation and are billed by the provider for payment by the carrier, to improve cost reporting for provider based home health agencies, and to improve cost information and statistical data for renal dialysis.

FY 1982 Medicare Annual Report - HHA and SNF Cost Limits

The Omnibus Budget Reconciliation Act of 1981 lowered the home health agency (HHA) cost limits from the 80th to 75th percentile. These lower limits were applied to services performed on or after October 1, 1981. The departure from the past practice of applying limits to an entire cost reporting period (rather than to services pegged to a specific date) required a one-time modification to the method used to complete HHA cost reports. With the exception of this change, the cost limits for HHAs and skilled nursing facilities (SNFs) were determined and applied in the same manner as in prior years.

The Tax Equity and Fiscal Responsibility Act of 1982 (TEFRA) made changes in the SNF and HHA cost limits programs. For cost reporting periods beginning on or after October 1, 1982, separate limits for hospital-based HHAs and SNFs were not permitted. Limits were to be based on the costs of freestanding providers. An add to the freestanding limits was permitted to recognize higher costs of hospital-based providers resulting either from differences in the case mix of patients treated from Medicare cost apportionment rules. Limits implementing the TEFRA changes were published in September 1982. (Later legislation, however, postponed the change with respect to SNFs.)

Schedule of Guidelines for Physical Therapy and Respiratory Therapy Services

Section 1861(v)(5) of the Social Security Act requires the Secretary to establish criteria for determining a provider's reasonable cost of services furnished by therapists or other health related personnel under arrangement with another provider, a clinic, a rehabilitation agency or a public health agency. Medicare allowable cost for this service may not exceed an amount equal to the prevailing salary the provider would normally incur if it furnished the services directly, plus allowances for fringe benefits, travel and other expenses. To implement this provision, HCFA, since 1975, has issued salary equivalency guidelines, first for physical therapy services and later for respiratory therapy services. On March 26, 1982, a notice was published in the Federal Register updating the existing guidelines by a factor of 13.1 percent for services furnished on or after October 1, 1981. In addition, instructions were issued in June and September 1982 addressing a number of factors concerning determination of allowable cost for these services, including travel expense rates, fringe benefit and expense factor, definition of administrative and supervisor responsibility, exception due to unique circumstances or special labor market exceptions and provider recordkeeping and reporting requirements.

2. Reasonable Cost Limits - Skilled Nursing Facilities - Proposed limits on skilled nursing facility (SNF) costs were published in 1979 and a final schedule became effective October 1, 1979. The final schedule also established limits for Medicaid skilled nursing facilities and intermediate care facilities (ICFs). The Medicaid State agencies, however, differ widely in their methods of determining allowable costs. Because of the technical problems these agencies encountered in the application of the published limits, the regulations were subsequently amended, suspending the application of the cost limits to Medicaid payments for SNF and ICF services.

   The SNF routine cost limits are very similar in design to those for hospital routine operating costs. The limits are derived from reported inpatient routine services costs of comparable facilities. Comparability is achieved by classifying SNFs according to location (urban or rural) and status as either a free-standing or hospital-based agency.

   The SNF limits resemble the 223 hospital limits in other respects as well. Capital related costs are excluded in deriving and applying the limits. The remaining costs are adjusted for inflation using a market basket index based on cost of goods and services which SNFs typically purchase. Differences in routine service costs resulting from differences in prevailing area wage levels are recognized using the same wage index incorporated in the hospital limits. Hospital wage data are used because of the lack of quality wage data suitable for indexing specific to nursing facilities and the similarity of the hospital and SNF labor markets. The level of the limits is also established using a mean based criterion which, effective October 1, 1979, was 115 percent of average group costs. A revised set of limits incorporating several refinements in the initial schedule and setting the level and 112 percent of group mean cost was published in the Federal Register on September 4, 1980 and became effective October 1, 1980.

   The limits effective October 1, 1981 retain the same methodology used in 1980.

Elimination of Inpatient Routine Nursing Salary Cost Differential

Section 103 of P. L. 97-248, the Tax Equity and Fiscal Responsibility Act of 1982, eliminated the inpatient routine nursing salary cost differential as an element of reimbursable cost under Medicare for hospitals and skilled nursing care facilities (SNFs). Prior to this legislative change, the Medicare rules for calculating reimbursable costs to these providers included this inpatient routine nursing salary cost differential because it was presumed that patients age 65 and over required more nursing services than the general patient population. The differential, which was also applied to maternity and pediatric patients, was not an add-on to the total routine nursing salary costs incurred by a provider, but rather it was a reallocation of the actual routine nursing salary costs between aged, pediatric, and maternity patients and all other classes of patients. Beginning on October 1, 1981, the differential was 8.5 percent for SNFs and 5 percent for hospitals.

The provisions of section 103 of P. L. 97-248 were implemented by the October 1, 1982 publication in the Federal Register of a final rule with comment period (47 FR 43618). This amendment was effective for cost reporting periods ending after September 30, 1982. For cost reporting period that begin before October 1, 1982 and end after September 30, 1982, a promotion will be used.

3. Reasonable Cost Limits - Home Health Agencies - Section 223 limits on home health agency (HHA) costs were first established effective July 1, 1979. These initial limits were based on a classification system which only distinguished between urban and rural providers and were set at the 80th percentile of per visit costs. The limits were derived from the per visit costs of agencies for each of six Medicare covered services: skilled nursing care, physical therapy, speech pathology, occupation therapy, medical social services, and services of home health aides. Cost data were obtained from the Medicare fiscal intermediaries. Inflation adjustments were based on actuarial estimates of increases in interim payments for home health services and a formula for voluntary price restraint in the health care sector established by the Council on Wage and Price Stability.

   Although HCFA calculated limits for each type of home health service, the various cost finding methods used by providers made it impractical to apply the limits directly to the per visit cost of individual services. Therefore, HHA cost limits were applied on an aggregate basis. That is, the limits for each type of service were multiplied by the number of visits for that service. The sum of the resulting amounts was then compared to the agency's aggregate allowable Medicare cost. However, mandatory uniform cost finding for HHAs effective October 1, 1980 will eventually permit the direct application of limits for each type of service.

   For the HHA limits effective July 1, 1980, HCFA adopted several features common to the hospital and skilled nursing facility methodologies. The revised system is based on an urban/rural classification system with separate categories for hospital-based and freestanding agencies. The new methodology also incorporates the hospital wage index to recognize differences in area wage levels (an HHA specific index is presently not available) and relies on an HHA market basket for inflation adjustments.

Unlike the hospital and SNF methodology, HHA per visit costs in each group were arrayed in descending order, and the limit was established at the 80th percentile for each type of service in each group.

Contracted Services Purchased by a Home Health Agency

Section 930(p) of Public Law 96-499 prohibits Medicare reimbursement for any costs incurred by a home health agency under a contract entered into after December 5, 1980, for services to be furnished for or on behalf of the agency (a) if the contract is entered into for a period exceeding 5 years, or (b) if the amount payable by the agency is calculated on the basis of a percentage of the agency's reimbursement, or claim for reimbursement, for services furnished by the agency. In January 1982, HCFA issued manual instructions to implement this provision effective for services furnished on or after April 1, 1982. Cost incurred under contracts entered into on or before December 5, 1980, and costs of contracts entered into after December 5, 1980, for services furnished prior to April 1, 1982, continue to be reimbursable to the extent they do not exceed the reasonable value of the services furnished.

Home Health Coordination Costs

Home health coordination, also known as intake coordination, is intended to facilitate the transfer of patients from a hospital or skilled nursing facility (SNF) to home health agency (HHA). In May 1982, HCFA issued manual instructions to define coordination activities performed by HHA personnel which ease a patient's transition to care in the home health setting, the cost of which are allowable to the HHA. The instructions differentiate those activities from patient solicitation activities, the cost of which are unallowable, and from discharge planning activities, which are the responsibility of the hospital or SNF and therefore are unallowable as an HHA cost.

Other Reimbursement Initiatives

1. Inpatient Routine Nursing Salary Cost Differential—Under Medicare Part A, hospitals and skilled nursing facilities (SNFs) are reimbursed based on the reasonable cost of health care items and services furnished to beneficiaries. The Medicare rules for calculating reimbursable costs of the providers include an inpatient nursing salary cost differential at a rate of eight and one-half percent. The differential is not an add-on to the total routine nursing salary costs incurred by a provider but rather a reallocation of the actual routine nursing salary costs between aged, pediatric, and maternity patients and all other classes of patients.

   Therefore, the formula for determining the inpatient routine nursing salary cost differential recognizes two inpatient general per diem costs:

   1. a higher than average cost applicable to aged, pediatric, and maternity patients; and

   2. a lower than average costs applicable to all other inpatients.

   Because it is a reallocation process, reimbursement of the differential to each provider is affected by the provider's total patient mix. For example, in a situation where 100 percent of a provider's patients are aged, pediatric, or maternity patients, there would be no reallocation and, as such, no differential payment by Medicare.

The 1981 Omnibus Budget Reconciliation Act (Section 2141) reduced the inpatient routine nursing salary cost differential as a reimbursable cost of hospitals, to a "... rate not to exceed 5 percent ..." effective October 1, 1981.

2. Reimbursement for Swing-Bed Services

On July 20, 1982, HCFA issued regulations implementing the swing-bed provision (Section 904 of P.L. 96-499) of the Omnibus Budget Reconciliation Act of 1980. Under this provision, small rural hospitals with less than 50 beds which have been granted a certificate of need for the provision of skilled nursing and intermediate care services from the State, and which have an agreement with DHHS, can use their hospital beds interchangeably as either hospital, skilled nursing or intermediate care beds. Reimbursement is based on the specific type of care provided. The provision was added to increase the number of nursing home beds in rural areas.

Another significant change in reasonable charge reimbursement was also made when Section 946 of P.L. 96-499 was implemented. Before enactment of that provision, the Medicare carriers determined reasonable charges for covered services on the basis of the customary and prevailing charge screens in effect at the time the claims for reimbursement were submitted. Instructions were issued to the Medicare carriers in March 1981 to provide, in accordance with Section 946, that reasonable charges must be determined on the basis of the charge screens in effect at the time the services are furnished. The only exception to this rule is that the carriers will not go back further than one year to determine reasonable charges for claims filed after long delays. The final regulation implementing this provision was published in the Federal Register on October 1,1982.

Elimination of Duplicate Overhead Payment for Outpatient Services (Section 104)

The provision requires the Secretary to issue regulations to eliminate the duplicate payment of overhead expenses from the recognized charges of a physician who performs services in hospital outpatient departments. Interim final regulations implementing this provision were issued on October 1, 1982.

Radiologist/Pathologist (Section 112)

The provision eliminates the 100 percent reimbursement rate previously applicable to inpatient radiology and pathology services. Medicare will pay for such services on the same basis as for other physicians' services, i.e., 80 percent of the reasonable charge after the Part B deductible has been met. Instructions to implement this provision were issued effective for services furnished on or after October 1, 1982.

3. Advertising Costs - Under Medicare principles of reimbursement, costs of advertising to the general public which seeks to increase patient utilization of a provider's facilities and services are unallowable. As a result of concerns raised by providers, HCFA revised the instructions on advertising costs to specifically indicate that reasonable cost of informational listings in the yellow pages or similar directories are allowable if the listings are consistent with practices that are common and accepted in the industry.

4. Cost to Related Organizations - When services, facilities and supplies are furnished to a provider by organizations related to that provider by common ownership or control, the costs may be claimed by the provider cost to the related organization (not to exceed the price of comparable services, facilities, or supplies that could be purchased elsewhere). Several administrative and judicial disputes resulted from certain ambiguities of this manual section. Therefore, we developed a manual revision to clarify several provisions of this broad principle. Specifically, we (1) provided more realistic and definitive examples of common ownership and control; (2) specified how the costs of a related supplying organization are determined; and (3) clarified the exception to the basic principle by providing examples of criteria for each exception. The major work on this matter was accomplished during FY 82, with the manual revision issued in December 1982.

5. Ambulatory Surgical Centers - Work was completed on the development of regulations implementing Medicare's ambulatory surgical center (ASC) provision during FY 1982. Proposed regulations, dealing with the standards such facilities must meet to be covered under the program, as well as the coverage and reimbursement of surgical procedures, were published on March 23. Final regulations, accompanied by the required list of covered surgical procedures and the reimbursement amounts for each, were published August 5, 1982 and went into effect September 7, 1982. By the end of FY 82, work was being completed on the forms and instructions required to administer the new benefit.

6. Salary-Related Reimbursement of Certain Therapy Services - During FY 81, HCFA continued work to implement salary equivalency guidelines for physical therapy and respiratory therapy services furnished under arrangements between providers and independent contractors. These guidelines were developed under authority contained in Section 1861(v)(5) of the Social Security Act. Section 1861(v)(5) requires HCFA to develop criteria for determining the reasonable cost of services furnished by therapists or other health care specialists (except physicians) under arrangments with a provider.

   Under the law, Medicare reimbursement for these services may not exceed an amount equal to the prevailing salary and fringe benefits that would have been by a provider had the services been performed by a provider employee, plus an allowance for other expenses related to furnishing these services. The definition of prevailing salary is based on the 75th percentile of the range of salaries paid to full-time therapists, using data compiled by the Bureau of Labor Statistics. The Medicare guidelines establishing these limits also contain a fringe benefit and expense factors. Additional allowances are made for travel, benefit, overtime equipment and supplies, aides and assistants furnished by the contractor, and administrative or supervisory responsibility.

During FY 81, HCFA issued updated guidelines for physical therapy and respiratory therapy. In addition, HCFA published in the Federal Register on August 13, 1981, proposed changes in the methodology used to establish the guidelines. Final criteria and guidelines were prepared following review and analysis of comments received in response to the notice.

7. Bonding and Escrow Requirements for Home Health Agencies - Section 930(n) of P.L. 96-499 gives the Secretary authority to establish requirements (including bonding and the establishment of escrow accounts) for home health agencies (HHAs) as appropriate for the financial security of the program. Section 930(p) provides that costs an HHA incurs in complying with these requirements are not reimbursable under Medicare. Moreover, an HHA subject to these requirements cannot be reimbursed for interest costs incurred in borrowing to repay an overpayment unless the HHA has been determined to have acted in good faith.

   The legislative history of the provision reveals that Congress was concerned that HHAs are often unable to repay overpayment without borrowing the funds to do so. HHAs for the most part are not well-capitalized, and many are dependent on Medicare to a significant degree (about 40 percent of all HHAs have Medicare utilization of at least 75 percent). When an HHA incurs a significant overpayment, it may borrow to repay the overpaid amount, or pay the amount back in installments, thereby jeopardizing its cash flow. If the overpayment is too large, the HHA may become insolvent. When an HHA borrows to repay an overpayment, it includes the interest expense in its costs, and Medicare reimburses the HHA a portion of those costs.

   A notice of proposed rule making was being prepared to establish financial security requirements consistent with Congress' concerns while minimizing the adverse financial consequences such requirements would have. The proposed regulation will describe categories of HHAs that potentially security requirements that are consistent with the degree of risk involved. Moreover, a variety of mechanism will be offered, not limited to bonds and escrow accounts in the literal sense, by which HHAs may satisfy the requirements.

8. Reasonable Compensation Guidelines - The reasonable compensation for services of key administrative personnel (including owners who render provider services) is recognized as an allowable Medicare cost. However, the amounts of compensation are subject to evaluation under the general requirement of the Medicare law that provider costs must be "reasonable." The evaluation of owner compensation between 1968 and the present has been based on compensation ranges resulting from regional surveys of compensation for administrative positions occupied by a nonowner.

Because compensation ranges developed on a regional basis are not standardized, it was decided it would be more effective to provide a statistically valid, standardized, nationwide approach to establish ranges which can be used by intermediaries in evaluating not only owner, but other key administrative personnel compensation.

During FY 81, a national survey of key administrative positions was undertaken to obtain statistically valid compensation data for each type and class of Medicare provider. The data collected will be used to develop reasonable compensation ranges to be used as guidelines, along with other criteria, such as specialized experience or education, by Medicare intermediaries in evaluating the allowability of compensation cost under Medicare regulations 42 CFR 405.426 and 405.451(c)(2).

9. Revision of the Medicare Home Health Agency Cost Report - In October 1980, HCFA published and distributed revised cost reporting forms to be used by all home health agencies that are not provider-based. The revised cost reporting forms, required for cost reporting periods beginning on or after October 1, 1980, implement final regulations published in August 1980. They provide a single method of allocating overhead costs and a single method of apportioning patient care costs between Medicare and non Medicare patients. The revised forms will assist in the application of cost limits to home health agencies by requiring uniform and improved methods of determining the cost by type of service.

Previously, home health agencies used a variety of cost reporting methods, making comparison of costs among home health agencies difficult. The revised cost reporting forms will allow HCFA to analyze the relationship of direct and indirect costs of furnishing patient care and to compare costs among home health agencies, and will enhance HCFA's ability to develop and apply limits to home health agency costs.

10. Reasonable Charge Reimbursement Initiatives

It is common practice for physicians to bill their patients for laboratory tests which have not been performed in their own offices or under their personal supervision but which are acquired for their patients from independent laboratories. In these instances, the physician forwards the specimen to the outside laboratory which, in turn, bills the physician directly for the services performed. As a rule, independent laboratories use lower price schedules when they bill physicians for test than they charge to the general public for similar services. These lower prices to physicians often reflect volume discounts and lower laboratory billing costs resulting from periodic billings.

In recent years, evidence accumulated by the General Accounting Office (GAO), the Congress and the Department has indicated that there are frequently substantial markups on bills submitted by physicians for these services. To help deal with this problem, the Congress enacted Section 918 of P.L. 96-499, the Omnibus Reconciliation Act of 1980, which precludes Medicare reimbursement of such markups.

The initial instructions to implement the new statutory provision were issued to the Medicare carriers in March 1981.

A final regulation implementing the provision was published in the Federal Register on August 23, 1981. The new rule provides that: (1) If a bill submitted by a physician indicates that a particular laboratory service was performed by (a) that physician, (b) another physician sharing the practice, or (c) an individual under the physician's supervision, the reimbursement allowed will be based on the reasonable charge for that service. (2) If a physician bills for a laboratory procedure that was performed by an independent clinical laboratory and identifies the laboratory and the amount charged for that service, payment will be based on the lower of (a) the laboratory's reasonable charge for the physician. In either case, the physician is also allowed a nominal amount for collection and handling of the specimen if he or she bills for such services. (3) If the physician does not indicate that he or she performed the test, and does not identify both the laboratory and the amount charged for the test, payment is to be based on the lowest amount which the Medicare carrier estimates the test could have been obtained from a laboratory serving the physicians's locality. A nominal specimen collection and handling fee will be paid to the physician only if the physician's bill indicates that the test was performed by an independent laboratory and not by the physician or peronnel under his or her supervision.

Another significant change in reasonable charge reimbursement was also made when Section 946 of P.L. 94-499 was implemented. Before enactment of that provision, the Medicare carriers determined reasonable charges for covered services on the basis of the customary and prevailing charge screens in effect at the time the carriers in March 1981 to provide, in accordance with Section 946, that reasonable charges must be determined on the basis of the charge screens in effect at the time the services are furnished. The only exception to this rule is that the carriers will not go back further than one year to determine reasonable charges for claims filed after long delays. The final regulation implementing this provision was published in the Federal Register on December 31, 1981.

Other Policy Initiatives/Issues

1. Ambulance Services - A Notice of Proposed Rule Making was published in the Federal Register on August 27, 1980 that would expand the ambulance service benefit. Coverage would be extended to include round-trip transportation of hospital inpatients to other facilities, including such nonhospital facilities as clinics or therapy centers, to obtain medically necessary diagnostic or therapeutic services not available in the facility, or to the patient's home. The regulation was proposed to recognize developments in medical care practice and health care planning which have made it necessry to provide round-trip transportation for hospital inpatients to other facilities to obtain services. It provides for one round trip transportation of a hospital inpatient to the nearest appropriate treatment facility to obtain medically necessary diagnostic or therapeutic radiological services. The regulation also specifies that, in the case of a beneficiary who is being transported to a hospital to become an inpatient, the availabiity of a physician or physician specialist capable of providing the necessary treatment required by the beneficiary's condition is a factor in determining whether the hospital has appropriate facilities to care for the beneficiary. A final regulation was prepared following review and analysis of comments received in response to the notice.

2. Oxygen Therapy in the Home - A notice published in the Federal Register on December 14, 1979, contained proposed policies and guidelines that Medicare Part B contractors would apply, where necessary, to claims for oxygen used in the home. The objective was to assure that uniform criteria are applied by contractors in determining whether a valid medical need for oxygen exists so that the home use of oxygen can be paid for by the program. The guidelines proposed medical conditions for which oxygen therapy is appropriate when used by the home patient and also proposed what would be acceptable medical evidence of the need for oxygen. This evidence would include a physician's prescription with specified information and blood gas study reports. The notice also contained a list of questions about different medical aspects of the proposed guidelines in order to obtain as complete a report as possible from the medical community. Criteria and guidelines in this area are being reviewed within the Department.

3. Exclusion of Heart Transplantation Procedures from Medicare Coverage - HCFA discontinued Medicare coverage of heart transplantation procedures effective June 13, 1980. The policy, announced in a HCFA Ruling published in the Federal Register on August 6, 1980, rescinded an earlier interim decision of November 2, 1979 that had authorized coverage for heart transplantation procedures only at Stanford University Medical Center. The Ruling authorized payment for heart transplantation and associated medical treatment at Stanford University Medical Center and at the University of Arizona Medical Center performed on or before June 12, 1980, or for candidates accepted on or before June 12, 1980. It excluded other heart transplantation coverage pending the results of further study.

   The Ruling further announced that HCFA, in close cooperation with the Public Health Service, National Center for Health Care Technology, would conduct a broad study of all aspects of Medicare coverage of heart transplants, including social, economic, and scientific issues. The study will also examine the impact of a coverage decision on beneficiaries, the Medicare program, and competing health care providers, and will include patient care costs for a limited number of Medicare beneficiaries accepted for transplantation at appropriate institutions.

   The study will consist of two parts. Institutions that agree to participate in Part I will make available data concerning heart transplants performed during the study period, as well as during the most recent five year period. In Part II, a qualified research organization will be selected to develop, evaluate and analyze a wide range of data furnished by institutions participating in the study and from other sources, and will forecast possible scientific, medical, economic and social issues that could affect reimbursement and influence Medicare coverage policy.

   When the study results have been analyzed, HCFA intends to publish a proposed decision on Medicare coverge of heart transplants and to solicit full public participation in development of the final policy, with all pertinent information made available for analysis.

4. Coverage Decision Procedures - During FY 81, HCFA has continued to improve its process for developing national Medicare coverage decisions concerning whether or not health care items and services are medically "reasonable and necessary." The Medicare law prohibits payment for items or services which are not reasonable and necessary for diagnosis or treatment.

   A Physician Panel, comprised of all HCFA physicians and dentists, as well as two physicians representing the Public Health Service (PHS), met regularly to discuss and recommend action on new coverage issues before HCFA.

   Written procedures have been established for referral of new coverage issues to the PHS after presentation to and recommendation by the Physician Panel. Procedures have also been established for issuance of HCFA coverage instructions based on advice and recommendations from the PHS.

   During FY 81, HCFA referred 28 new coverage issues to the PHS, and published 53 instructions based on advice received from the PHS. An additional number of coverage issues was disposed of without the need for published instructions.

5. Prohibition Against Payment for Less than Effective Drugs - On June 5, 1980, HCFA published in the Federal Register a proposed rule to prohibit the payment for certain drugs under the Medicare and Medicaid programs. The rule would bar the expenditure of Federal funds under the two programs for drugs determined by the Food and Drug Administration (FDA) to be not effective for any indicated use, and prohibit reimbursement for drugs with certain exceptions that have not been approved by the FDA for sale in interstate commerce. A number of comments were received in response to the proposed rule but before a final regulation could be prepared based on comment analysis, this policy initiative was superseded by enactment of Section 2103 of the Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35). Effective October 1, 1981, this provision prohibited Medicare Part B payment and Medicaid payment for prescribed drugs for which the Secretary has issued a Notice of an Opportunity for a Hearing (NOOH) on a proposed order to withdraw the drug from the market because the FDA has determined that the drug is less than effective for all indicated uses and for which the Secretary has not determined there is a compelling justification for its medical need. This will include any other drug product that is identical, similar or related. Procedure instructions were issued to Medicare carriers and Medicaid State agencies, containing a list of drug products and known related products lacking substantial evidence of effectiveness and subject to an NOOH.

   The implementation was from Section 115 of the Tax Equity and Fiscal Responsibility Act of 1982 which is Public Law 97-248 which provides for its implementation.

6. Provider Reimbursement Appeals - Under the Medicare program, the amount paid to a provider of services is the reasonable cost of items and services furnished to beneficiaries. To be reimbursed for covered services, providers must file cost reports with their fiscal intermediaries to determine the amount of reimbursement. If a provider is dissatisfied with the amount of reimbursement (or if the intermediary does not make its determination timely), the provider has the right to request a hearing before one or more hearing officers designated by the intermediary, or before the Provider Reimbursement Review Board (PRRB), if the amount in controversy is $10,000 or more. The statute authorizes the Secretary to reverse, affirm, or modify a decision of the PRRB. This authority has been delegated to the Administrator of HCFA, the official having administrative responsibility for the Medicare program. If a provider is dissatisfied with the Administrator's decision, or the PRRB's decision, if it is not reviewed by the Administrator, the provider may request review of the final agency decision by a United States district court.

   On February 14, 1980, HCFA published in the Federal Register (45 fr 9953), a number of proposed regulatory additions and revisions designed to improve the review process. All relevant public comments have been taken into account and a revised regulation is under review.

   Section 955 of P.L. 96-499, the Omnibus Reconciliation Act of 1980, amended Section 1878(f)(1) of the Social Security Act. The amendments make it possible for a provider that requests and has the right to obtain a hearing by the PRRB under Section 1878(a) of the Act to bypass the hearing and obtain judicial review of any action of the fiscal intermediary involving a question of law or regulations relevant to the matters in controversy, whenever the PRRB determines that is without authority to decide the question. The PRRB may determine that it does not have the authority to decide a question, either on its own motion or upon the request of a provider.

   In FY 81, HCFA had prepared a regulation document detailing the procedures by which a provider may bypass the PRRB hearing.

7. Waiver of Liability Procedures Applicable to Erroneous Placement in an Inappropriately Certified Bed of a Participating Hospital or SNF -Section 956 of the Omnibus Reconciliation Act of 1980 (P.L. (96-499) was enacted December 5, 1980, and became effective January 1, 1981. It amended Section 1879 of the Social Security Act by adding new paragraph (e), which has the effect of permitting program payment when a beneficiary, who otherwise qualifies for Medicare coverage, is precluded from program payment solely because the beneficiary received the services in a part of an institution not qualified to provide the appropriate level of care for purposes of Medicare. The provision applies to hospital and SNF levels of care, and incorporates into law requirements almost identical to those stemming from the earlier Wright v. Califano court ruling on SNF claims involving erroneous placement in noncertified beds which had taken effect on September 11, 1979. Payment under the amended Section 1879 is limited to cases in which the appropriate placement was the result of unintentional, inadvertent, or erroneous action by a provider of services

acting in good faith based on the advice of a utilization review committee, physician, Professional Standards Review Organization or fiscal intermediary, or was the result of a clearly erroneous administrative decision by a provider of services.

HCFA issued interim administrative instructions in March 1981, implementing this provision of the law. A Notice of Public Rule Making (NPRM) was proposed NPRM.

8. Provider Reimbursement Appeals

HCFA published a regulation in the Federal Register on July 22, which implements section 955 of P.L. 96-499. The law relates to situations in which the Provider Reimbursement Review Board determines that it does not have authority to decide the point at issue. The PRRB may determine that it does not have the authority, either on its own motion or upon the request of a provider. In that circumstance, a provider that requests and has the right to obtain a hearing by the PRRB may bypass the hearing and obtain judicial review of any action of the fiscal intermediary that involves a question of law or regulations relevant to the matters in controversy.

D. IMPROVING UTILIZATION SAFEGUARDS

One of the most critical areas of the Medicare program activity is to establish safeguards against improper and excessive utilization of health care services. A part of the rapidly increasing costs of Medicare continues to be attributable to the furnishing of medical services for which Medicare claims submittals are made, which are not medically necessary by reference to generally accepted medical practice norms, or which are medically inappropriate, particularly in terms of location of care. Most overutilization does not represent any criminal intent to defraud the Medicare program. Usually they represent "decisions of opportunity," i.e., when a service opportunity is presented which is reimbursable by an external party and there is lack of rigorous definition about the nature of the service opportunity is presented which is reimbursable by an external party and there is a lack of rigorous definition about the nature of the service or the reimbursement rules for that service, there is an incentive to render the service with a high degree of expectation that it will be reimbursed. The delivery of medical care is particularly subject to this incentive because the necessity and appropriateness of such services are often judgmental matters. Additionally, some medical practices which tend to induce overutilization have become traditional in the American health care delivery system.

Under the Part A hospital insurance program, one of the most obvious examples of this is unnecessary occupancy of expensive inpatient facilities, when health services at that level of care are not required. An admission to a hospital for services which could be given in a skilled nursing or intermediate care facility or on an outpatient basis, with equal medical effectiveness, is a particularly striking example of such a situation. A Friday admission to a hospital whose costs are inappropriately generated. Extended stays in a facility beyond the patient's medical need for that facility's level of care creates a far higher care cost than should be incurred by either the patient or the insurer.

In FYs 80 and 81, nearly seven million brochures entitled "Thinking of Having surgery? Think About Getting a Second Opinion" were distributed to welfare offices, SSA district offices, consumer and professional groups, and individuals throughout the United States. Public service announcements promoting the second opinion program and publicizing the national toll-free number (800-638-6833) were distributed to 730 television stations and over 6,000 radio stations.

Patients wishing second opinions can contact local referral centers or call the national toll-free number to obtain the name and telephone number of their local referral center. Approximately 28,000 calls have been made to the national "hotline" since the inception of the program in October 1979.

In the medical insurance program, excessive or unnecessary utilization often occurs because the common charge structure for medical services, whether in an outpatient hospital setting or in respect to services furnished by private physicians, is generally that fee is charged for each visit. Under such a system, program reimbursement can be substantially increased solely as a result of an increased number of visits. That increase in number of visits may or may not represent a proportionate increase in either the quantity or quality of medical services rendered. Thus, patients may initiate physician or outpatient visits which their medical needs have been met. Additionally, physicians and outpatient clinics may invite or allow more patient visits than are required for the patient's medical management or which customary practice would ordinarily dictate.

The program approached its responsibilities in the area of utilization safeguards in a number of ways. The structure of the program itself provides some fundamental controls on general utilization. There are benefit limitations on the number of days of care in hospitals and extended care facilities and for home health visits. These limits are intended to assure coverage for the vast majority of medical situations that require these levels of service and yet provide upper limits beyond which program payment would not be made. The program prescribes deductible and coinsurance amounts which may serve as a safeguard against the initiation of unnecessary services because they require patients to share the cost of services and, thus, provide some motivation for them not to seek services unnecessarily or prolong services beyond their medical needs. Particularly significant are the program requirements that, for services to be reimbursable, they must be furnished on a physicians's order or under the direction of a physician, and the physician must certify that they are medically necessary. Additionally, for inpatient services to be reimbursable, a Professional Standards Review Organization (PSRO), if there is one in the area, must certify that they are medically necessary. Finally, Section 1862(a)(1) of the Social Security Act provides that under both the hospital and medical insurance programs, payment may not be made for services which are not reasonable and necessary for the diagnosis and treatment of illness and injury.

During FY 82, HCFA continued to refine the prepayment screens which carriers utilize to identify situations of potential overutilization or variations from medical necessity norms.

A particularly important screen, utilized by many Part B carriers, permits the prompt identification of individual physicians whose total bills for Medicare patients in given periods significantly exceed what would normally be expected in ordinary practice. Investigation of physicians identified by means of such a screen can disclose instances of overutilization or cases in which the State or local medical society or even cases of deliberate fraud in which prosecution would be appropriate. The increasing awareness that cases involving possible excessive rates of payment are being investigated constitutes a significant deterrent to overutilization.

Other types of screens which are being increasingly used by carriers provide for the identification of (1) physician-patient contacts which appear abnormally frequent for a particular diagnostic category or therapeutic procedure, (2) potential markup situations where physicians include an added charge for services actually provided by an independent laboratory, or (3) situations in which a physician begins charging separately for component services which had previously been rendered as a combination of package service with a single charge. Carriers are increasingly incorporating such screens into their electronic data processing systems.

It is important to recognize that in many instances variations from usual patterns are justified by the facts of an individual case. The important thing, however, is that the Medicare claims review process must be able to identify significant variations so that further review can be undertaken in instances of possible excessive or improper utilization.

HCFA is also continuing its efforts to assure that Medicare payment is only made for items and services which are medically necessary and of acceptable professional quality. This activity takes a variety of forms. First, PSROs have stringent quality review requirements, and set objectives to be met. These studies, which must demonstrate impact, range from reducing avoidable deaths to reducing avoidable postoperative infections. Additionally, HCFA continues to identify individual items, services, and procedures which are of questionable value. When HCFA obtains medical evidence that an item, service, or procedure is not safe and effective or that it is experimental, it discontinues payment for it. HCFA conducts these activities with the support of the Public Health Service and in collaboration with national medical and medical specialty societies.

Another dimension of the medical necessity issue relates to determinations as to whether items or services provided to a beneficiary in a specific case are medically necessary. In recent years, criteria have been developed to assist Medicare intermediaries to make these determinations. This is a very sensitive area, of course, since such determinations may directly challenge the medical judgement of the physician who ordered or rendered the services. Because this is such a sensitive area, review criteria are developed by physicians, and denials are only made on the basis of a physician's professional judgment. The PSRO program, established in 1972, provides for organizations to develop and apply medical necessity criteria to services rendered in hospitals and nursing homes.

The inducements to the provision of services beyond medical need are considerable. These inducements range from pressure but on physicians by patients who are familiar with popularized diagnostic and therapeutic procedures and exotic new technologies, to the increasing concern by physicians over potential malpractice suits for failure to provide the entire gamut of diagnostic and therapeutic procedures to every patient. The latter leads to what has been called "defensive medicine." Other inducements are the use of expensive new equipment beyond medical justification in order to amortize the high cost of such equipment and, for some, the inducement of simple avarice, under the rationalization that the additional service, even though unnecessary, does not harm the patient medically or financially, since he or she "has insurance."

In dealing with these problems, HCFA works closely with professional organizations to assure that services are provided and reviewed in accordance with the best professional judgment.

E. QUALITY AND APPROPRIATENESS OF CARE

A major goal of the Medicare program is to assure that its beneficiaries receive appropriate health care services. This is assured by requiring that those facilities caring for Medicare beneficiaries are structurally safe, clean, properly staffed, and provide needed services and that the actual care delivered to beneficiaries meets accepted professional standards. In addition to assuring the quality of services received, HCFA must make sure that services are necessary and performed at the most economical level consistent with good care. These efforts ensure a high quality of care for beneficiaries while simultaneously constraining health care costs.

Standards and Certification

In accordance with the Social Security Act, any facility providing health care services to Medicare beneficiaries must meet certain health and safety standards before it is eligible to receive reimbursement from Medicare. In order to ensure that these standards are met, HCFA provides for periodic survey of each facility. These surveys are conducted by each of the States under contract with the Department. In the case of hospitals, however, the law allows the privately-run Joint Commission on Accreditation of Hospitals (JCAH) and American Osteopathic Association's (AOA) standards and surveys to be considered as having met the Federal government's requirements. Therefore, States only survey those hospitals not accredited by JCAH or AOA and will, on a sample basis, conduct surveys on JCAH and AOA hospitals in order to validate that the surveys conducted by these associations continue to meet Medicare requirements.

Generally, the Federal Standards and Certification program is responsible for establishing and updating Federal health care standards, developing State survey procedures, and monitoring surveys and standards enforcement. During FY 82, program emphasis was placed on (1) upgrading standards affecting the quality of services, (2) developing more efficient and effective survey procedures, (3) reducing regulatory burdens and eliminating duplicative requirements to lessen unnecessary expenses imposed by certain standards. Discussion of major FY 82 activities includes.

1. Conditions of Participation

Conditions of participation establish the requirements for life safety, medical care, nursing care, and physical and social environment that facilities must satisfy to participate in Medicare. During FY 81 two major conditions targeted for regulatory review were:

- Hospital Conditions of Participation - simplification of requirements which hospitals must meet to be certified to participate in Medicare and Medicaid.
- Skilled Nursing Facility/Intermediate Care Facility (SNF/ICF) Conditions of Participation - revisions of present regulations governing conditions for participation of SNF and ICF facilities under Medicaid and Medicare programs.

2. Survey and Certification Procedures (Subpart S)

Survey and certification procedures for Medicare and Medicaid were developed at the time these programs became law. The survey process is an effort to apply the standards and conditions of participation for the Medicare program. Since development of these procedures, some elements have been found to be either unnecessary, or duplicative. In order to address these concerns, this process is also undergoing major review.

In the spring of FY 82 HCFA proposed a series of revisions to the public survey and certification process. The major issues addressed for revision were identified during hearings held in the spring of 1980. These revisions include: (1) provisions mandated by 1980 and 1981 Omnibus Reconciliation Acts; (2) the elimination of nonproductive requirements; (3) consolidation of Medicare and Medicaid certification rules; and (4) elimination of unnecessary differences between Medicare and Medicaid requirements.

3. Professional Standards Review Organizations (PSROs)*

In 1972, Congress enacted legislation calling for the establishment of PSROs to ensure that the health care services provided to Medicare and Medicaid beneficiaries were: (1) of a quality that meets professionally recognized standards of care, (2) medically necessary, and (3) appropriately provided in the most economical setting. PSROs were comprised of practicing physicians who engaged in various activities associated with the review of care in a given locality. The law provided that PSROs were responsible for the reviews of health care services delivered in hospitals and long-term care facilities.

As a result of the Omnibus Budget Reconciliation Act of 1981, PSROs were required to review only those health services provided to Medicare patients but were no longer required to perform Medicaid reviews, effective October 1, 1981. State Medicaid agencies then had two options: (1) contracting with PSROs for the continued performance of medical or utilization review functions and therefore being deemed to meet the Utilization Control (UC) requirements for those services and providers that the PSRO reviewed, or, (2) States could assume direct responsibility for assuring the UC required by Title XIX of the Social Security Act. Any agreements entered into with a PSRO prior to October 1, 1981 continued to exist until the next renewal date of the agreement or in accordance with instructions in the existing grant.

*In 1982, Congress enacted legislation creating utilization and quality Control Peer Review Organizations (PROs) to replace the existing PSRO program. PROs are responsible for assuring that care provided to Medicare patients is medically necessary and reasonable, is provided in the appropriate setting, and meets acceptable standards of quality. PROs are either composed of licensed, practicing physicians in their areas, or have available to them the services of physicians in each major speciality. There are a total of 54 PROs (one for each state, the District of Columbia, Puerto Rico and the Virgin Islands, and one that covers Guam, American Samoa, the Northern Mariana Islands, and the Trust Territories of the Pacific.)

4. Second Surgical Opinion Program

In FY 78, HCFA began a major information campaign to encourage consumers to seek a second opinion before undergoing nonemergency surgery. The campaign was particularly directed to Medicare and Medicaid beneficiaries. The campaign is premised on the patient's right to know the benefits and risks of the recommended surgery and any alternatives to that surgery. HCFA's second surgical opinion program centers around the major efforts:

- a national second opinion referral system
- a public information campaign

In FYs 81 and 82, nearly seven million brochures entitled "Thinking of Having Surgery? Think About Getting a Second Opinion" were distributed to welfare offices, SSA district offices, consumer and professional groups, and individuals throughout the United States. Public service announcements promoting the second opinion program and publicizing the national toll-free number (800-638-6833) were distributed to 730 television stations and over 6,000 radio stations.

Patients wishing second opinions can contact local referral centers or call the national toll-free number to obtain the name and telephone number of their local referral center. Aproximately 28,000 calls have been made to the national "hotline" since the inception of the program in October 1979.

F. REPORT ON MEDICARE/MEDICAID VALIDATION SURVEYS OF HOSPITALS ACCREDITED BY THE JOINT COMMISSION ON ACCREDITATION OF HOSPITALS (JCAH)

A. Introduction

The purpose of the validation program is to determine the effectiveness of the JCAH accreditation process and whether accreditation assures that hospitals comply with Medicare Conditions of Participation. Each year, a representative sample of the 5,000 JCAH accredited hospitals is selected for validation surveys. The number of hospitals receiving a validation survey was significantly reduced in fiscal years (FYs) 1981 and 1982; therefore, it was necessary to combine 2 years of activity to have sufficient information to conduct a meaningful analysis. Under contract with the Secretary, State Agencies (SAs) conducted 76 validation surveys during the report period (FYs 1981 and 1982).

Prior to January 1, 1982, the maximum period of JCAH accreditation was 2 years, which was given to hospitals fully meeting JCAH standards. A hospital found to be in substantial compliance with JCAH standards, although demonstrating certain shortcomings, received a 1 year accreditation. On January 1, 1982, JCAH discontinued both 1 and 2 year accreditations, and changed its accreditation program to a 3 year accreditation program with a "contingency" procedure. A contingency is a condition that JCAH attaches to the accreditation to monitor improvements in the area(s) of concern identified during the survey. Under JCAH's new accreditation program, a hospital may receive a 3 year accreditation without a contingency; receive a 3 year accreditation with a contingency; or lose JCAH accreditation.

They further strengthened existing monitoring mechanisms to include periodic self-survey reports and/or focused onsite surveyor revisits. In both circumstances, a hospital which fails to achieve substantial overall compliance would lose its accreditation.

The lengthening of the JCAH accreditation period from 2 to 3 years halfway through this report period created problems for analyzing the data. Specifically, it is difficult at this time to isolate any effect of this change.

B. Statutory Background

Section 1865 of the Social Security Act provides that JCAH accredited hospitals are "deemed" to meet the requirements of the conditions of participation in the Medicare program, except for utilization review or other standards the Secretary promulgates that are higher than JCAH standards. Thus, JCAH accredited hospitals are not subject to annual State agency (SA) surveys to assess compliance with the conditions of participation.

Subsection 1864(c) of the Act authorizes the Secretary to enter into an agreement with any State under which the appropriate State or local agency which performs the certification function described in subsection (a) will survey, on a selective sample basis (or where the Secretary finds that a survey is appropriate because of substantial allegations of the existence of a significant deficiency or deficiencies which would, if found to be present, adversely affect health and safety of patients), hospitals which have an agreement with the Secretary under section 1866 and which are accredited by the Joint Commission on the Accreditation of Hospitals.

C. Validation and Allegation Process

The Health Care Financing Administration selects a statistical sample of accredited hospitals for validation surveys from scheduled JCAH accreditation surveys. The random selection reflects our urban-rural mix of hospitals, and hospitals of different sizes. This permits us to apply our findings to the universe of JCAH hospitals. SAs survey these hospitals using the Medicare Conditions of Participation. If significant deficiencies are found that affect the health and safety of patients, the hospital is placed under SA surveillance until the deficiencies are corrected. The hospital is no longer deemed to meet the Medicare Conditions of Participation and the SA monitors the correction of any deficiency as if the hospital were unaccredited.

Seventy-six (76) hospitals received validation surveys during the report period. We have compared the results of Medicare and JCAH findings by analyzing deficiencies found by both agencies. Our analysis was conducted in two discrete areas: Life Safety Code (LSC) and general health and safety requirements.

1. Life Safety Code

The LSC is a body of standards that provide a reasonable level of safety from fire and other emergencies.

During this report period, 55 (72 percent) validated hospitals were in compliance with LSC. For all hospitals validated prior to this report period, only 42 percent (275 of 655) were in compliance with LSC. This improvement can be attributed to the increased effectiveness of JCAH surveyors in assessing compliance with the LSC and Medicare's adoption of the Fire Safety Evaluation System (FSES) for validation surveys.

The FSES was developed by the National Bureau of Standards and is a method for assessing compliance with the LSC which allows a facility to employ alternative measures for meeting LSC requirements while still ensuring an equal degree of fire safety.

Medicare recommended in 1980 that JCAH surveyors receive additional training in surveying for smoke barriers. These construction requirements are important because the smoke barriers limit the spread of smoke and toxic gases. Inhalation of these gases is the most frequent cause of death in fires. In this report period, HCFA and JCAH surveyors found a similar number of smoke barrier deficiencies indicating the benefit of the additional training. We are encouraged by the greater correlation of HCFA and JCAH LSC findings and the increased number of JCAH citations in smoke barriers. There continues, however, to be a disparity in the deficiencies cited relating to sprinkler systems. The need for additional JCAH surveyor training in this complicated, but vital area is indicated by these findings.

LSC compliance has increased 46.9 percent so that for this report period it is only 7 percent less than general health and safety compliance (see Table 1), compared to the previous report period compliance disparity of 24 percent.

2. General Health and Safety

During this report period, 79 percent of JCAH accredited hospitals receiving validation surveys were found in compliance by Medicare with general health and safety conditions. This is an overall 7.6 percent increase in compliance over the previous report period.

Within the general health and safety conditions for validated hospitals, the laboratory and nursing conditions are most frequently found out of compliance (See Table 2). Laboratories and nursing findings are consistent between current and prior report periods as well as between accredited and unaccredited hospitals.

HCFA and JCAH both consider the hospital laboratory as a single entity, regardless of the number of specialty labs or satellite facilities. Hospitals may have 10 to 30 different laboratories (i.e., serology, hematology, chemistry, microbiology, blood bank, etc). Thus, if one of these laboratory areas or specialty laboratories is out of compliance, the entire laboratory condition is out of compliance.

A review of the laboratory survey findings for this report period indicates that the majority of deficiencies were in chemistry, hematology, and microbiology and consisted of both quality control and recordkeeping problems. These deficiencies are basically the same ones the SAs found in hospital laboratories not accredited by JCAH and in independent laboratories.

The relatively high rate of noncompliance with the nursing condition is associated with bed-size. The majority of the validated hospitals that were out of compliance in nursing have a bed size range from 7 to 38. The same problem exists in small, rural unaccredited hospitals.

D. Substantial Allegation Findings

An accredited hospital is also subject to a SA survey when a complaint is made alleging that significant deficiencies exist which threaten the health and safety of patients. Surveys made in response to a complaint cover only the conditions related to the complaint. If a significant deficiency is found in this partial survey, then the SA performs a full survey. As with a validation survey, if the SA discovers any significant deficiencies, the hospital continues to be subject to SA surveillance (as if it were an unaccredited hospital) until the deficiencies are corrected.

For this report period, 249 hospitals received complaint investigations of which only 14 percent were found out of compliance with one or more conditions. This reflects an 8 percent decrease compared with the last reporting period.

Only 1 percent of these hospitals were found out of compliance with Life Safety Code. Over the previous 4 report period, an average of 7 percent of these hospitals had LSC deficiencies. This 6 percent decrease parallels the improvement in validation findings.

Nine percent of these hospitals were out of compliance with nursing, which is consistent with previous reporting periods.

For all other general health and safety conditions, the rate of noncompliance ranged from 1 percent to 3 percent found out of compliance.

E. Conclusion

Considering both validation surveys and complaint investigations, we found that only 20 percent of all hospitals surveyed were placed under SA surveillance, as compared with 35 percent for the prior report period. This decrease demonstrates increased equivalency between the JCAH and Medicare survey processes. Except for LSC, Nursing and Laboratory conditions, both validation surveys and substantial allegation investigations found all other conditions out of compliance in only 6 percent or less of hospitals found out of compliance.

Accredited hospitals have few problems meeting HCFA standards, other than LSC. Indeed, in many areas, JCAH standards exceed HCFA's requirements. With regard to surveying for the LSC, JCAH has substantially strengthened its capabilities to both evaluate and enforce the LSC requirements. Compliance findings with respect to the LSC on validation surveys for the current report period show that 28 percent of the validated hospitals were out of compliance. This result is 26 percent below the average of the previous 4 report periods indicating continued improvement in JCAH's ability to survey for this condition.

Although there is a significant decrease in the number of hospitals found out of compliance with the LSC compared with previous report periods, JCAH surveyors should continue to receive additional training in some aspects of the LSC. We recommend that JCAH conduct training in surveying sprinkler systems. As demonstrated by validation survey findings regarding smoke barriers, training improves JCAH ability to survey adeqately for this requirement. JCAH LSC survey capability can be further enhanced by training in sprinkler systems and other construction-related requirements.

Overall, the findings during this report period indicate an improvement over prior reporting periods. The percentage of hospitals placed under SA surveillance as a result of both validation and complaint investigation surveys was 20 percent of those hospitals surveyed. In prior report periods, this ranged from 29 percent to 55 percent. This reflects a general strengthening of the JCAH enforcement capabilities.

It is through JCAH and HCFA survey efforts that health care facilities continue to improve. The validation program is a check and a healthy stimulus for both JCAH and the SAs. Without the basis for exchange and comparison of results, both programs would suffer. As long as the standards and program management of both agencies continue to develop and improve, the objectives and intent of both organizations will benefit.

The hospital validation program and the JCAH accreditation program are operating successfully. By monitoring both programs closely, HCFA is alert to any significant changes, and takes immediate corrective actions if problems are identified.

TABLE 1

Validation Surveys

Accredited Hospitals Found In Compliance By Medicare State Survey Agencies

		Previous Report Period FY 1980		Current Report Period FYs 1981 & 1982		Percent Difference
		No.	%	No.	%	
General Health & Safety	In Compliance	58	73	60	79	7.6
	Total Surveys	79		76		
Life Safety Code	In Compliance	39	49	55	72	46.9
	Total Surveys	79		76		

TABLE 2

Validation Surveys Compared to all Unaccredited Medicare Surveys

Compliance with Laboratories and Nursing Conditions

		Previous Report Period FY 1980					Current Report Period FYs 1981 and 1982				
		JCAH Val.		Unaccred.MedicareSurv.			JCAH Val.		Unaccred.Medicare Surv.		
		No.	%	No.	%	% Diff.	No.	%	No.	%	% Diff.
Laboratories Condition	In Compliance	71	89	1403	93	3	68	89	1411	93	4
	Total Surveys	79		1511			76		1521		
Nursing Condition	In Compliance	73	92	1399	93	1	71	93	1468	96	3
	Total Surveys	79		1511			76		1521		

G. INCREASING HMO ENROLLMENT BY MEDICARE BENEFICIARIES

Health Maintenance Organizations (HMOs) are continuing to increase in number as an alternative to traditional forms of health care delivery. An HMO is an organization which provides its members comprehensive health services, without regard to frequency or extent of services, in return for a predetermined, fixed premium paid by its members. Under traditional methods of health care delivery, an individual buys health insurance from one organization, but has services provided by other individuals and institutions, each of whom bills separately. An HMO, by contrast, is both a health care insurer and a health care provider, with members receiving covered services through the HMO. Because the amount its members pay for the cost of care is fixed in advance, there is great incentive for HMOs to reduce the cost of care. They strive to reduce costs by emphasizing preventive care and health education, by providing only medically necessary care, and by using ambulatory care rather than more expensive inpatient hospital and other institutional care whenever possible.

Congress recognized that the HMO emphasis on keeping down health care costs could produce significant savings for Medicare. Therefore, in 1972 Congress authorized the Medicare program to enter into contracts with the HMOs, allowing them to be reimbursed on a capitation basis for all covered services under Part A and B of Medicare furnished to beneficiaries who enrolled in HMOs. Member beneficiaries pay a premium which covers Medicare deductible and coinsurance amounts.

During FY 82, the number of contracting HMOs was 59. Medicare membership in HMOs increased from 92,564 to 127,606, an increase of 38 percent.

During 1982, the Health Care Financing Administration continued its emphasis on beneficiary enrollment in HMOs. There were 2.5 million beneficiaries living in HMO service areas notified by mail of the availability of HMO services. Medicare enrollment in HMOs is expected to continue to increase substantially.

H. FRAUD AND ABUSE CONTROL ACTIVITIES

During FY 82 HCFA's only involvement with Medicaid/Medicare fraud was the referral of potential fraud cases to the Office of the Inspector General for possible criminal prosecution, or to the Department of Justice for possible civil prosecution. HCFA's attention has been focused on the detection and prevention of abuse in the Medicaid/Medicare programs with concerted efforts in the areas of:

- integrity involving preliminary case development and abuse case processing;
- administrative sanctions actitivies (terminating/excluding/suspending certain physicians or practitioners from participation in the Medicare program);
- quality assurance programs;
- increased efforts in various validation reviews;
- identifying overpayments and savings;
- applying computer technology to detect patterns of fraud and abuse; and
- legislative proposals.

Results

In carrying out the responsibilities outlined above, the Health Care Financing Administration achieved the following:

Workload

1. Integrity reviews (IRs) processed by HCFA regional offices and Medicare contractors -- 32,585
2. Overpayments identified as a result ot IRs processed --$4,438,696.
3. Full-scale abuse cases processed by HCFA regional offices and Medicare contractors -- 2,903.
4. Overpayments identified as a result of full-scale abuse cases processed -- $19,385,174.

Quality Assurance Programs

Contractor Performance Evaluation Program (CPEP)

In FY 82, HCFA evaluated the performance of Medicare contractors by using the Contractor Performance Evaluation Program. In this program, specified criteria are used to measure contractor Part A (hospital insurance) and Part B (medical insurance) performance in the areas of: bill processing (claims processing - Part B), utilization safeguards -Part B only, provider reimbursement (program payment - Part B), beneficiary services, fiscal administration, and general administration. These criteria are applied uniformly to all contractors within each program. Standards for unit cost of bill (claim) processing, timeliness of bill (claim) processing, timeliness of cost report settlements (Part A only), and quality of claims processing (Part B only) were also established. The process of applying standards and criteria to intermediary performance began on October 1, 1979. Carrier performance initially became subject to the application of standards and criteria on October 1, 1980. Each subsequent year the standards and criteria have been revised and refined to more accurately measure contractor performance.

The CPEP is administered through HCFA's ten regional offices. Throughout the fiscal year, the regional staffs evaluate contractor performance by conducting onsite reviews and analyzing performance data. At the end of the year, Annual Contractor Evaluation Reports (ACERs) are prepared citing CPEP results and are published by the regions of each contractor in their service area.

HCFA uses the results of the application of CPEP criteria and standards to the contractors' performance to identify the contractors having deficient performance. When combined with historical perspective, this process has proven to be an effective tool for identifying those contractors exhibiting a pattern of continuing poor performance with little or no apparent improvement. Establishment of performance goals and monitoring systems, and the practice of conducting face-to-face meetings between senior HCFA staff and executives of poor performing contractors, have achieved overall improvements in contractor operations.

The program integrity performance levels for intermediaries (Part A) seek to ensure that:

1. desk reviews of provider cost reports are performed to verify that providers are receiving appropriate program reimbursement;
2. full-scale indepth audits are performed when appropriate;
3. improper or nonallowable costs are identified and necessary adjustments are made;
4. instances of potential fraud and abuse are identified and referred for investigation; and
5. sanction action (exclusion or termination from participation in the program) is taken when appropriate.

The program integrity performance levels for carriers (Part B) seek to ensure that carriers:

1. monitor the Medicare claims experience for all individual and group physician/suppliers, and acquire statistical data on them and their specialty groups;
2. identify and review those physicians by locality and specialty whose utilization patterns differ from medically recognized standards, criteria and norms;
3. correct any program abuse or overutilization of provider service by recovery of overpayments;
4. prevent further abuse in the utilization of services by educating physicians/suppliers in the acceptable norms of practice;
5. identify those individual providers or types of services where prepayment controls are necessary;
6. refer cases for sanction action (exclusion from participation in the Medicare program) if corrective action has been unsuccessful; and
7. properly handle and refer for investigation, fraud and abuse complaints received from beneficiaries, interested parties, or other sources.

As part of the Medicare Administrative Reform Initiative which was extensively underway during fiscal years 1981 and 1982 within the Health Care Financing Administration (HCFA), the annual Medicare contracting process was being utilized as one means to achieve greater efficiency in the administration of the Medicare program. By June 30, 1982, we notified 25 Medicare contractors (or subcontractors with the Blue Cross Association (BCA) that we planned to non-renew their contracts beyond FY 1983 or place limitations on their contract renewals for FY 1983. Our decision to take these contract actions resulted from analysis of three critical areas:

- quality of contractor performance of Medicare functions;
- contractor cost-effectiveness in administration of the program; and
- optimal contractor configuration for program administration.

The consolidation of contractor territories resulting from our contract actions lead to a reduction of 15 Medicare contractors (from 108 to 93) to be effectuated by the end of FY 1983 with an anticipated annual administrative savings in FY 1984 and thereafter of $3 to $4 million.

Cost Report Evaluation Program (CREP) - Part A

The Cost Report Evaluation Program (CREP) is a comprehensive review program, designed to evaluate the quality of the settlement of provider cost reports (Part A - Title XVIII) by Medicare intermediaries. CREP has been in operation since FY 79 and is now beginning its fourth year.

CREP was initially designed to evaluate hospital cost report settlement and this is still its primary focus. In recent years, the program has been expanded to include Home Health Agency (HHA) settlements.

CREP scores are fed into Contractor Performance Evaluation Program (CPEP) as the only evaluation measure under intermediary audit and reimbursement functions. (CPEP is operated by HCFA's Bureau of Program Operations which evaluates all contractor functions.) The major objectives of the program are to:

1. ascertain that intermediaries are settling cost reports in accordance with program regulations, policies and instructions,

2. discover errors and recoup program monies where applicable,

3. identify the underlying cause of significant errors or problems and make recommendations for improvement, and

4. identify areas in the regulations, instructions, and policies which are either not clear or require clarification or revision.

The reviews are performed by the ten HCFA regional offices, with central office assisting when necessary. Central office staff is responsible for reviewing HCFA's Office of Direct Reimbursement intermediary functions.

The CREP, which is starting its fourth year of operation, was originally designed to evaluate Medicare hospital settlements. There are approximately 6,800 hospitals in the United States which receive about $27 billion as payment for inpatient services to Medicare beneficiaries. CREP is the only program that consistently evaluates this significant cash flow stream. CREP is to be expanded to include Home Health Agency (HHA) settlements, a Systems Test for Alternative Reimbursement (STAR), and will expand into Long-Term Care facilities and chain operations.

The program is based on a valid statistical sample of provider cost reports that were settled by Medicare intermediaries within certain designated periods. The program consists of a series of objective procedures that are designed to evaluate significant areas of provider cost reimbursement. Regional office reviewers are required to evaluate all applicable areas based on their analysis of cost reports, desk reviews, intermediary workpapers, permanent files and other pertinent documentation. At the conclusion of the review, a report of findings and recommendations is issued to each intermediary. The report also includes a score which is based on the regional evaluation of the procedure.

During FY 82, there were 71 intermediaries reviewed. The total number of hospital providers reviewed was 522 and the total number of HHA providers reviewed was 27. Total estimated dollar recoveries were $10 million. As a result of CREP, 12 policy issues were identified for clarification and have been resolved.

Medicare Part B Quality Assurance Program

The Part B Quality Assurance Program was designed to provide a statistically valid and objective procedure for evaluating carrier claims processing performance. The carrier performance measurements data are obtained through systematic carrier reviews of samples of adjudicated claims drawn from each carrier's universe of Part B claims. Regional Office subsample reviews verify the accuracy of the performance data from the carrier reviews. Data is provided on the number and type of processing errors and associated dollar amounts for each carrier's claims processing operation and compared on a national basis through consolidating rankings. The data generated constitute an integral part of the Contractor Performance Evaluation Program (CPEP) which, in turn, is a primary mechanism for determining carrier contract renewal, discontinuance, or required program improvements. The Quality Assurance Program also provides carriers with a management tool to improve the quality of their claims processing operation and, in addition, gives HCFA a useful basis for modifying policies and adjusting procedures in the development of a more cost effective and efficient Medicare Program.

A national quarterly report is published which ranks carriers based on the cumulative error rates assessed during the most recent 12-month period. Carriers are ranked both on occurrence error rate (processing errors per 100 line items in the universe) and on payment/deductible error rate (dollar errors per 100 dollars of submitted charges in the universe). A penalty figure is included in the payment/deductible error rate when a carrier fails to review all sample claims selected.

The following information is for FY 82:

- Forty Medicare Part B carriers (55 processing sites) processed 180 million claims with submitted charges totaling $22 billion.
- Carrier occurrence error rates ranged from 2.5 to 14.4. The mean occurence error rate was 7.0.
- Carrier payment/deductible error rates ranges from 0.5 to 5.7. The mean payment/deductible error rate was 1.7.
- Payment/deductible dollar errors, representing overpayments and underpayments and misapplication of the deductible, totaled $434 million. The mean number of payment/deductible dollar errors was $22 million.
- Tracking the 10 carriers with the highest overpayment error rates for the FY 81 review period resulted in $12.6 million in savings during the FY 82 review period.

During FY 82, the total payment/deductible error rate with penalty decreased 0.2 percent from FY 81. The mean carrier error rate decreased from 1.9 to 1.7 percent. A savings to the Medicare Part B program of $10 million occurred in this period due to a decrease in the national overpayment error rate. The FY 82 national error rate (overpayment error rates only), based on 50 of 55 carrier locations reporting, was .9 percent. This indicates that $.90 was estimated to be overpaid per $100 of submitted charges. For FY 81, this error rate was 1.0 percent.

Chain Operations

In FY 82, HCFA has continued its efforts to improve its ability to cope with the complex activities of the chain organizations and to properly relate these activities to the Medicare reimbursement process. Selected audits of chain home office cost statements were reviewed. These reviews were intended to validate the quality of the intermediaries audit efforts and find those reimbursement issues that are particular to chain organizations.

Program Validation

During FY 82, HCFA continued its extensive validation review program to detect fraud, abuse and waste among providers, and to identify and correct inappropriate and potentially wasteful policies and procedures. The major types of validation reviews are:

a. Systematic Abuse Reviews (SARS) (noninstitutional): SARS are conducted to identify providers with aberrant utilization or billing practices and to evaluate contract review systems and/or improve such systems.

b. Aberrant Cost Studies (ACS) (institutional): During an ACS, providers are reviewed to determine if overutilization or aberrant cost or billing practices exist. Additionally, the appropriateness of contractors/State agency reimbursement and audit is evaluated.

c. Program Implementation Reviews (PIRs): These reviews are conducted to determine if reimbursement policies and/or the implementation of such policies contribute to inappropriate levels of reimbursement.

In FY 82, validation review efforts resulted in the following:

- Thirty-six SAR reports were finalized. Medicare overpayments or other program savings of approximately $13.3 million were identified.
- Fifty-three ACS reports were finalized. Overpayments or other program savings of approximately $4.4 million were identified.
- Forty-six PIR reports were finalized. Overpayments or other program savings of approximately $33.6 were identified.

The above figures reflect a total of 135 final validation reports produced during FY 82 which identified total Medicare overpayments or other program savings of $51.3 million. (This figure is the amount of "identified" overpayments and savings. It may not be collectible because of the death or retirement of physicians/practitioners, bankruptcy, dissolution of corporations, flight from prosecution, negotiated settlements, etc.).

Identifying Overpayments and Savings - (overpayments and savings identified by the Management Inefficiencies, Program Misuse and Fraud (MIPMF) System).

HCFA reported savings from two major MIPMF initiatives to the Office of Management and Budget during FY 81.

1. Overpayments Identified: The Medicare overpayments and savings identified in FY 81 under the MIPMF initiative totaled $22,605,832. This figure is 140 percent higher than a projected goal of $9.4 million. The MIPMF figure is approximately $1 million more than the total overpayments shown in Section a. (above) because overpayments resulting from Medicare fraud cases were included.

2. Savings resulting from terminations, exclusions and suspensions of Providers: Actual Medicare savings as a result of this initiative totaled $3.18 million in FY 81, compared to projected savings of $3.38 million. This represents a five percent decrease in targeted savings vs. actual savings. This decrease in expected savings is due to reduction in the termination, exclusion and suspension actions implemented in FY 81 vs. FY 82.

Black Lung Overpayments

HCFA identified substantial overpayments, involving millions of dollars per year, with respect to services that should have been paid for by the Department of Labor (DOL) under the Black Lung program. Instances of payments by both programs for the same services were also identified. HCFA was instrumental in establishing arrangements with DOL to permit recovery of overpayments from DOL rather than from the beneficiary or the provider. A number of recommendations were made regarding temporary and permanent long-term solutions to the overpayment problems. In June 1983 procedures were implemented which identify dually entitled beneficiaries and prevent Medicare payments where DOL has responsibility for payment.

Computer Technology

Software programs have been developed to detect instances of fraud or abuse in the Medicare and Medicaid programs. These programs have detected inconsistent billing practices in the Part A and Part B files; Part A, Part B, and Medicaid files; Part A and Black Lung files; and Part A and Worker's Compensation files.

Legislative Proposals

Several significant legislative proposals were developed in FY 82, including:

- Denial of Payments to a Provider for Services Ordered by a Sanctioned Physician

  This proposal would authorize the Secretary to deny reimbursement under Medicare and to deny Federal Financial Participation under Medicaid for all items and services ordered by a physician during the period that such physician was suspended or excluded from Medicare program participation under existing authorities. The proposal would also allow denial of Medicare reimbursement and Federal Financial Participation under Medicaid for inpatient services whenever the patient was admitted to the provider of such services by a suspended or excluded physician. Current authorities prohibit Medicare and Medicaid reimbursement directly to a suspended or excluded physician. However, the sanctioned physician may continue to abuse the Medicare and Medicaid programs by ordering unnecessary or excessive items or services and unnecessary hospital admissions for beneficiaries and recipients. This proposal would address this problem.

- Secretary's Authority to Terminate a Provider's Agreement

  This proposal would enable the Secretary to terminate those health service providers owned, controlled, or operated by an individual who has been convicted of criminal offense related to his/her involvement in the Medicare or Medicaid program. This proposal is needed to correct a technical deficiency in current similar authorities.

- Denial of Program Participation to Entities Where Owners or Certain Other Individuals Have Been Convicted of a Program Related Offense

  This proposal would correct a gap in existing legislation. The Secretary would be allowed to deny program participation to suppliers and other entities where a person, with significant ownership or control interest in the supplier or other entity, or who is an officer, director, agent, or managing employee of the entity, has been convicted of a program-related criminal offense.

- Civil Money Penalty for Medicare and Medicaid Fraud and Withholding of Payments for Certain Medicaid Providers -- see Appendix G, Significant Legislation Enacted in FY 81, Omnibus Reconciliation Act of 1981, Section IV.

I. BENEFICIARY SERVICES

Established in December 1979, the primary objectives of the Office of Beneficiary Services (OBS) are:

1. Inform beneficiaries about HCFA programs, and their rights and responsibilities.
2. Open channels of communication between beneficiary representative groups and HCFA.
3. Improve services provided to beneficiaries by contractors, State Agencies and Social Security Offices.

Medigap

HCFA has developed an education program to better inform Medicare beneficiaries about (1) Medicare coverage, (2) the major gaps in Medicare coverage, (3) the various types of private health insurance assigned to supplement Medicare and (4) comparative shopping hints to use when purchasing private supplemental health insurance. To implement this initiative, OBS designed, developed, and produced the 68-page training text, Medicare and Private Health Insurance, based on a pamphlet developed jointly with the National Association of Insurance Commissioners (NAIC). This text, plus acccompanying visual aids and checklist for comparing policies, served as the basic material for a nationwide program to train counselors and volunteers who, in turn, assist Medicare beneficiaries on private health insurance decisions. To date, HCFA regional office Medigap coordinators (who received their initial Medigap training at central office) have conducted more than 470 training sessions in all 50 States, the District of Columbia and Puerto Rico. Approximately 22,000 attendees have received Medigap training through this program. A continuation of another facet of the Medigap initiative has been the distribution of over 9 million copies of A Guide to Health Insurance for People with Medicare, the information pamphlet which was first produced in 1979 in conjunction with NAIC.

Updating, Revising, and Improving Beneficiary Informational Material

OBS revises and updates Your Medicare Handbook semi-annually and all other Medicare pamphlets at least annually. Six million copies of Your Medicare Handbook were printed and distributed to Social Security offices, Medicare Contractors and new Medicare enrollees during FY 82.

When major changes in the Medicare program occur, a new pamphlet is often printed. Recent Changes in Medicare was prepared during FY 82 because of special informational needs created by the 1980 and 1981 Reconciliation Acts.

OBS also helps the public stay informed about current changes through Medicare/Medicaid Notes which is a monthly fact sheet explaining specific issues or recent changes in Medicare or Medicaid policy and procedures. This is distributed to all HCFA Regional Offices and approximately 40 National organizations (e.g., American Association of Retired Persons and National Council of Senior Citizens which have publications or newsletters for their members).

Beneficiary Casework

OBS continued to function as a central office ombudsman for special beneficiary inquiries and problem cases. Most inquiries are telephone referrals from the Office of the Administrator, HCFA; Office of the Secretary, HHS: the White House; and Congress. Many inquiries come directly from beneficiaries seeking help with errors in their records resulting in loss of eligibility or incorrect premium billings necessitating a review and correction of their Medicare records. There is also a high incidence of complaints about what are seen as deficiencies in program coverage; e.g., the lack of prescription drug or nursing home coverage under Medicare. In such cases, efforts are made to guide the caller to other resources for financing the necessary medical services. Other inquiries relate to difficulties with Medicare contractors and problems involving submission of, and reimbursement for, Medicare claims. In all these instances, the ombudsman function provides a valuable service for Medicare and Medicaid beneficiaries, many of whom have difficulty dealing with the complexities of these programs.

Liaison With Beneficiary Organization

OBS maintains an ongoing program of liaison with beneficiary organizations. In addition to soliciting beneficiary organization input and participation in the development of program policy procedures through briefings and personal liaison, Medicare periodically mails materials to national beneficiary groups to keep their membership informed about current Medicare benefits and coverage. OBS representatives also attend national organization conferences and meetings, and participate in workshops, panel discussions and forums on Medicare-related issues.

Beneficiary Services Awards

The Beneficiary Services Awards were established to provide special recognition to individuals or groups for either outstanding performance in service to beneficiaries or for a major contribution in the area of beneficiary services. The awards serve to provide an incentive to develop innovative ideas, resources, and programs in assisting beneficiaries.

OBS recognized outstanding beneficiary service again in FY 82 as part of HCFA's Annual Awards Ceremony. The Beneficiary Service Certificate of Merit was presented to four HCFA employees and ten nongovernment employees for their contributions to the improvement of services in the Medicare and Medicaid programs. This final group of ten represented Medicare contractors, State agencies, and beneficiary groups from ten different States.

Telephone Directory Listings Under Medicare

In July 1982, all Medicare Part B contractors were instructed to have their local and toll-free telephone numbers displayed with "Medicare" in the White Pages of the telephone directories which cover their service areas.

SSA District Office Final Adjudication of ESRD Initial Claims

In November 1981, the SSA district offices were given the capability to take final adjudicative action on certain initial end-stage renal disease (ESRD) awards. HCFA proposed this change in procedure and coordinated its implementation with SSA. District office final authorization has resulted in a decrease in processing time for initial ESRD awards. Many ESRD patients now have Medicare records established more quickly and medical bills for dialysis or transplant can be processed with less delay.

Centralization of the Direct Billing and Collection Operation

Until September 1982, the Social Security Administration printed and mailed bills from its Baltimore headquarters to 825,000 Medicare beneficiaries who are billed directly for their Medicare premiums. These punch card bills and premium payments were then returned to eight different SSA Program Service Centers for processing. This punch card operation was converted to a centralized lockbox (all premiums paid and processed by a private bank) operation. The beneficiaries were provided a portion of the new bill as a receipt, the bill is easily readable and is processed using automated equipment. The beneficiaries now receive the bills at least five days earlier and all funds collected by the lockbox bank are deposited to the Treasury Department within 72 hours. The conversion of the operation to a lockbox resulted in yearly savings of about $1, 550,000.

J. MEDIGAP VOLUNTARY CERTIFICATION PROGRAM

(Section 1882(i)(2)of Title XVIII)

Background

Congressional studies conducted prior to 1980 found many abuses existing in the sale and marketing of Medicare supplement or "Medigap" health insurance. There were no federal standards for medicare supplement coverage and few states had adopted programs to specifically regulate these types of policies. In June of 1980, Congress enacted Public law 96-265 which added Section 1882 to Title XVIII of the Social Security Act. This law, usually referred to as the Medigap Law, initially was staunchly opposed by insurance regulators and the insurance industry. The regulation of the business of insurance has traditionally been the responsibility of the states under the McCarran-Ferguson Act of 1945 and the Medigap law was perceived by some as an encroachment upon states' rights. This perception resulted from a fear that the Federal government would necessarily have to become greatly involved in individual insurance department operations in order to enforce the law. This has not proved to be the case, however, and the relationship between the Federal government and the states has been a viable one. State and Federal agencies are working together toward our common goal of providing the best protection available for our elderly citizens.

The Medigap law established federal minimum standards based primarily on the provisions contained in the 1979 National Association of Insurance Commissioners (NAIC) Model Regulation to Implement the Individual Accident and Sickness Insurance Minimum Standards Act. The law, however, expands upon the Model's requirements by extending its jurisdiction to certain group policies and by adding loss ratio requirements for both group and individual policies. In addition, it provides for the establishment of the Supplemental Health Insurance Panel, a Federal Voluntary Certification Program for Medicare supplement policies, and includes criminal penalty provisions for certain abusive sales practices.

Voluntary Certification Program

Under this program, insurers selling Medigap policies in these States may voluntarily submit such policies to be reviewed by the Secretary of the Department of Health and Human Services (DHHS). Those policies found to meet or exceed the Federal minimum standards would be certified and the insurer would be authorized to display a Federal emblem on the policy. The emblem is authorized for use only in states subject to the Federal program, regardless of whether the same policy is marketed in other states not under the program.

The Medigap Law also established Federal criminal penalties for certain fraudulent or abusive marketing practices. Criminal sanctions are provided for furnishing false or misleading information for the purpose of obtaining certification; for misrepresentation as an agent of the Federal government for the purpose of selling insurance to supplement Medicare; for knowingly selling insurance which substantially duplicates benefits of another policy held by the purchaser; and for knowingly advertising, soliciting, or offering for sale mail order policies in a state without the approval of the State insurance Commissioner. Anyone convicted of violations of Section 1882 is subject to a fine of up to $25,000 and/or imprisionment for up to 5 years.

Reporting Requirements

Section 1882(f)(2) of the Social Security Act requires the Secretary to submit to Congress no later than July 1, 1982, and periodically as may be appropriate thereafter (but not less than once every 2 years), a report evaluating the effectiveness of the certification procedure and the criminal penalties established under this section.

1. Voluntary Certification Program

The Supplemental Health Insurance Panel determined that the Voluntary Certification Program should be implemented in the following 4 States and 3 Territories: Massachusetts, New York, Rhode Island, Wyoming, Guam, the Virgin Islands and American Samoa. In the FY 81 Medicare Annual Report it was noted that California and New Jersey were also expected to be subject to the Voluntary Certification Program. However, these two States subsequently initiated their own programs meeting the federal minimum standards and the Panel recommended that the Voluntary Certification Program not be implemented in either state.

Only two insurers have submitted policies for review under the Voluntary Certification Program and no policies have been certified to date. While the deficiencies noted in the policies submitted were seemingly minor, the insurance companies involved have not re-submitted the policies or indicated that they have made the necessary changes. Other incurrers have expressed interest in the program, however, and it is felt that if one insurer were to market a certified policy, others would soon follow suit.

The fact that the Voluntary Certification Program applies only to a very few States and jurisdictions, in itself, limits the direct impact that such a program may have. In this same respect, however, the Voluntary Certification Program was responsible for the overwhelming success of the Medigap Law, since it served as the incentive for such a large number of States to adopt their own programs regulating Medigap policies. Indeed, the number of States adopting the 1979 NAIC Model is the largest number ever to adopt any NAIC model.

In addition to the small number of States involved, there are other possible reasons for such a limited reaction to the program. Foremost is the perception on the part of the state insurance regulators and the insurance industry that such a program is an infringement upon the individual States' right to regulate the business of insurance. As noted earlier, the Federal-State relationship resulting from the Medigap Law has proved an amiable one, but there is still much apprehension in the insurance community about a "federal" emblem being placed on a private insurance policy. It is felt that the emblem may encourage the practice of "twisting" where insurance agents replace existing coverage with new coverage that offers no greater benefits or even lower overall benefit levels. Some insurers also feel that the emblem may serve to confuse some elderly Medicare beneficiaries since it may appear only on those policies sold in states subject to the Voluntary Certification Program.

Most insurers design their Medigap policies to be marketed in a number of States. So a situation would exist where a policy would be able to display the emblem in a State under the federal program, but the exact same policy could not bear the emblem in a state that was not under the program. The additional costs involved in preparing policies for distribution in just a few States also is a deterrent to seeking certification.

Conclusion

Since the Secretary has not yet certified any policies under the Voluntary Certification Program, there is no data available to show the impact of the certification procedure on market share, value, and cost to individuals entitled to benefits under Title XVIII. As stated earlier however, the indirect impact of the program has been its very positive effect of prompting the States to implement their own approved regulatory programs for Medicare supplement policies. Without the Voluntary Certification Program serving as an incentive, it is doubtful that there would have been as many States making changes to their existing programs. Also, the Supplemental Health Insurance Panel is now responsible for monitoring the continued compliance of the approved States and the Voluntary Certification Program should act as a deterrent to those States considering changes to their regulatory programs that would adversely affect their continued compliance with the Medigap Law. At the present time it seems to be in the best interest of all concerned to continue the Voluntary Certification Program as set out in Section 1882.

2. Penalty Provisions

The Health Care Financing Administration (HCFA), given the responsibility for implementing the penalty provisions of the Medigap Law, continues to investigate possible violations of Section 1882(d). HCFA has developed a system of coordination for reporting these violations which includes the ten HCFA regional offices, the Social Security Administration (SSA, the Office of the Inspector General (OIG) for Department of Health and Human Services, and the Department of Justice (DOJ).

The initial screening of complaints is generally done through HCFA's regional offices. These offices are also responsible for furnishing information to state insurance departments about specific complaints. The OIG investigates complaints that have been referred to them by HCFA and coordinates this activity with state insurance departments. OIG also serves as the liaison between state insurance departments and the U.S. Attorneys, who have been contacted by the Fraud Division of DOJ regarding the medigap Law and encouraged to prosecute violations of this section.

During FY 82, HCFA was informed of 25 possible violations of the penalty provisions. Twenty-four of these, or 96 percent, involved Section 1882(d)(2) which prohibits a person from falsely representing an association with the Medicare program or any Federal agency for the purpose of selling or attempting to sell health insurance. One case involved an alleged violation of Section 1882(d)(3) which prohibits a person from knowingly selling duplicative health insurance to an individual entitled to Medicare, where such a policy will not pay duplicate benefits.

Of the complaints received: 15 are being or have been investigated by specific state insurance departments, 6 were closed by HCFA due to lack of evidence, 3 are being investigated by or have been investigated by the OIG, and one case investigated by the OIG and the FBI resulted in the indictment of three insurance agents in Pennsylvania.

HCFA also receives many complaints which, while not in violation of the Medigap law, are possible violations of other federal statutes. These most often involve misleading advertising and mail order solicitations for Medicare supplement insurance. HCFA's efforts in this area are being coordinated with other federal agencies such as the Federal Trade Commission and the Postal Inspection Service.

Conclusion

Witness reliability has continued to be a problem in getting cases prosecuted under Section 1882. The elderly often become confused under questioning and prosecutors are reluctant to charge agents under federal law, since criminal penalties are called for. They feel that administrative penalties are more appropriate in many cases.

There is still a great deal of interest at the state level in utilizing the federal penalties to prevent abuse and fraud in the sale and marketing of Medigap policies. Most States still do not have specific laws for violations involving Medicare supplement health insurance, as we indicated, however, getting these types of cases prosecuted under federal law has proven difficult. At the present time it is felt that it is in the best interest of our elderly citizens to continue the penalty provisions of Section 1882. Even though there have been no convictions to date under this law, the option of prosecution under federal law should remain available.

READEX FICHE

CHAPTER III. REPORT ON RESEARCH, DEMONSTRATIONS AND STATISTICS

Total spending for all health care expenditures in the United States rose from $74.7 billion in calendar year 1970 to $322.4 billion in calendar year 1982, an average annual rate of increase of 13.0 percent (Health Care Financing Review, Fall 1983).

- Medicare's share of all national health expenditures rose from 10.0 percent in 1970 ($7.5 billion) to 16.2 percent in 1982 ($52.2 billion).
- Medicaid's share of all national health expenditures rose from 7.3 percent in 1970 ($5.5 billion) to 10.5 percent in 1982 ($34.0 billion).

During FY 82 HCFA's Office of Research and Demonstrations (ORD) directed over 300 intramural and extramural projects that studied, demonstrated and evaluated reimbursement, coverage, eligibility and management alternatives to the present structure of the Medicare program. ORD also measured and evaluated the impact of HCFA's programs on (1) beneficiary use of program benefits and access to services, and (2) provider charges and program reimbursements for the use of these benefits.

As part of its ongoing research, demonstrations and evaluation program in FY 82 HCFA approved almost 70 new projects. These activities are described below in each of nine major research and demonstration program areas. Following that discussion is a section devoted to data base and statistical activities and a description of HCFA's publications program.

Research, Demonstrations and Evaluations

Research and experimentation in support of the Medicare program is authorized in the Social Security Act and the Social Security Amendments of 1967 and 1972, as well as in the National Health Planning and Resources Development Act of 1974. HCFA develops and tests innovative ways to promote efficiency and quality in the Medicare and other HCFA programs. It assesses the impact of HCFA programs on health care costs, program expenditures, beneficiary access to services, health care providers, and the health care industry. Reports are written to describe and analyze the use and costs of program benefits. Studies are undertaken to explore in greater detail the structure and dynamics of the various sectors of the health care industry.

During FY 82 HCFA spent almost $30 million for grants and contracts to conduct research, demonstration and evaluation projects in the following nine program areas:

- Beneficiary Impact
- Health Systems Organizations
- Hospital Costs
- Industrial Organization and Reimbursement
- Integrated Data Management Systems
- Long Term Care
- Physician Reimbursement
- Program Evaluation
- Quality and Effectiveness

Although projects discussed in this report related primarily to Medicare, information regarding Medicaid is also provided where it enhances the information being presented. Additional information on HCFA research and demonstration projects can be obtained from the HCFA publications office identified at the end of the chapter.

1. Beneficiary Impact

HCFA maintains a research program to assess the impact of HCFA programs on the beneficiaries and to determine the extent to which HCFA programs meet their goals. Data are collected and studied to analyze patterns and trends in the use of covered services and to measure the financial burden on the beneficiaries for medical care. Studies are designed to address these basic issues and to assess other issues important to the health of the beneficiaries, including access to needed care and the timely delivery of cost-effective and efficacious services.

A major study was begun in FY 1982 to analyze the use and costs of services in the last year of life. Using data from the continuous Medicare history sample, which links together all services reimbursed for Medicare beneficiaries over several years, the study will focus on decedents and trace back health care use in their last 12 months of life. Important questions to be studied are the extent of hospitalization in the last days of life, the magnitude of expenditures, and variations in expenditures by cause of death.

Since the beginning of the Medicare program, understanding the patterns and trends in the use of hospital services has been of prime importance. Two large studies were completed in FY 1982 which provided detailed new data and analyses about Medicare hospital use. Both studies were published in the March 1982 Health Care Financing Review. The first study, "The Rise in the Incidence of Hospitalizations for the Aged, 1967 to 1979" focused on the growth in the rate of hospitalization for Medicare beneficiaries and indicated that the increase found for the age group 65 years and over was greater than for younger age groups. Most of the increase in the rate of hospitalization, as measured by the number of discharges per 1,000 aged beneficiaries, was associated with an increase in the percentage of persons hospitalized rather than in the rate of multiple hospitalizations. Examination of changes in diagnostic and surgical case-mix showed that there was a large increase in vascular and cardiac surgeries. Changes in the demographic composition of the Medicare population did not help explain the differences in the rate of growth of hospitalizations.

The second study, "Trends and Regional Variations in Hospital use Under Medicare" focused on the large regional differences in Medicare hospital admission rates, in average length of stay, in days of care rates, and in average per capita reimbursements. The major conclusion from this study was that no one of these utilization statistics alone is adequate for supplying information on the many current policy issues facing the health care system. Rather, each one of these utilization variables can have a significant impact on the efficiency and effectiveness of the health care delivery system.

Another major area of study in ORD involves HCFA beneficiaries' enrollment in Health Maintenance Organizations (HMOs). HCFA has initiated several demonstration projects to encourage HMOs to participate in the Medicare program under a risk payment mechanism. HCFA's payment mechanism is known as the Adjusted Average Per Capita Cost (AAPCC). The AAPCC adjusts the payment to HMO for Medicare enrollee for five factors known to influence the level of Medicare outlays: age, sex, institutional status, welfare status and county of residence.

In 1982, ORD completed a study which analyzed the use of services by Medicare enrollees who joined three HMO demonstration projects: The Fallon Community Health Plan, the Greater Marshfield Community Health Plan, and the Kaiser-Permanente medical program of Portland, Oregon. The results of the study, "Pre-Enrollment Reimbursement Patterns of Medicare Beneficiaries Enrolled in At-Risk HMOs" was published in the September 1982 Health Care Financing Review. In two of the HMOs there was evidence of a favorable selection process. An earlier study of Medicare beneficiaries enrolled in the Group Health Cooperative (GHC) of Puget Sound, Washington also produced strong evidence of a favorable selection process.

As a result of these studies, ORD has launched a series of studies, in coordination with the University Health Policy Consortium, Brandeis University, to determine if there are valid and reliable ways of refining the AAPCC. The research activities were underway in FY 1982 and focus on three areas: (1) developing a model for including prior use in the computation of the AAPCC; (2) investigating the use of health status measures in the AAPCC; and (3) evaluating several methodological and statistical aspects of the AAPCC.

2. Health Systems Organization

Projects within this program area seek to improve the access of Medicare beneficiaries to health services, and at the same time, provide incentives to reduce the total cost of health care. Some studies explore alternative approaches to the organization and delivery of health care, while others modify payment methods of current health care institutions and practitioners.

In FY 82, as a result of a single solicitation, HCFA ORD awarded 21 Medicare Alternative Health Plans (AHPs) competition contracts which resulted in 30 provider site service agreements. The majority of the contracts were with Health Maintenance Organizations (HMOs). Demonstrations with HMOs are designed to promote competition within the health care marketplace by providing incentives for increased enrollment of Medicare beneficiaries and to reduce Medicare benefit costs by instituting alternative reimbursement methods. Due to their potential for cost-savings, HMOs can often offer extra benefits or cost-savings to beneficiaries and yet contract with Medicare at a reimbursement rate lower than the average fee-for-services cost.

Projected enrollment for all AHP competition demonstrations exceeds 200,000 Medicare beneficiaries. The demonstrations indicate that HMOs will contract with HCFA to enroll Medicare beneficiaries if: (a) current reimbursement policies are modified to permit risk reimbursement without requiring the preparation of the Medicare cost report; and (b) flexibility is granted that changes current reporting requirements.

Three major demonstration initiatives were launched in the area of expanding ambulatory service coverage to Medicare beneficiaries: Alcoholism, Mental Health Services, and Urban Health Clinics services.

Both the Alcoholism Services and Mental Health Services demonstrations are aimed at testing the cost-effectiveness of providing Medicare and/or Medicaid coverage for mental health services provided in ambulatory centers that currently do not have provider status. The hypothesis in both projects is that services can be provided effectively and efficiently at less cost in these settings than in traditional hospital inpatient or outpatient treatment settings.

HCFA has initiated its Urban Health Clinics demonstration which will examine the relative advantages and disadvantages of reimbursement on the basis of costs and fee-for-service for physician-directed clinics employing physician assistants or nurse practitioners. These clinics will be located in medically underserved areas in two States, Tennessee and California. Urban health clinics staffed with physician extenders may provide services in a more cost-effective manner. The evaluation is being conducted by A.D. Little, Inc. of Cambridge, Massachusetts.

HCFA and the Robert Wood Johnson Foundation continued to support demonstrations to determine whether primary care clinics affiliated with municipal outpatient departments could improve access to care and contain costs in urban areas. Twenty clinics in five cities are currently providing routine and ancillary services in this demonstration. In the aggregate, ancillary charges have been highest for dentistry and dentures, followed by pharmacy. Four of the five participating cities have attained the Robert Wood Johnson Foundation critiera for success: their Municipal Health Services Project (MHSP) clinic costs per visit are two-thirds or less of the cost per visit for that city's municipal hospital outpatient department and emergency room services. In addition, it was originally hypothesized that the improved access to primary care clinics would result in a decrease in the MHSP users' total cost and utilization of all inpatient and emergency room services. From preliminary results, it appears this hypothesis is true in four of the cities.

HCFA has sponsored three demonstrations which changed ESRD benefits by extending coverage to the services of a dialysis aide for maintenance dialysis sessions performed in the patients' homes. The primary purpose was to test whether or not providing this extra benefit resulted in more patients choosing home dialysis as a treatment option. In addition, the impact on cost and quality of care were documented for analysis.

The evaluators summarized their findings as follows:

- The cost of dialysis in the home setting was less than two-thirds the maintenance dialysis cost in the facility setting when the experimental provision of aide payment was excluded from the calculation. When aide payments were included, the cost of the home setting was just over 70 percent of the cost of facility dialysis;

- The proportion of home-based patients in the paid aide experimental group increased approximately 5 percent while the proportion of home-based patients in the control group decreased approximately 2 percent during the demonstration;

- There appeared to be little or no differences between hospital-based and free-standing facilities in the demographic and medical characteristics of hemodialysis patients;

- Home-based hemodialysis patients were found to be generally younger, in better physical condition, and have higher personal and family income levels than facility-based patients; and

- Fewer home-based hemodialysis patients experienced changes in marital status (divorce and separation) than facility-based patients. Both patient groups experienced increases in unemployment rates after the initiation of dialysis treatments. Changes in marital and employment status were generally attributed by patients to be a result of renal disease and the requirements of dialysis.

3. Hospital Costs

For fiscal year ending September 30, 1982, when inflation generally was 5 percent, hospital costs rose 14.8 percent. In the last three fiscal years (9/30/80, 9/30/81), 9/30/82), Medicare expenditures for hospital services have increased by 19.2 percent.

Prospective Payment

HCFA's Research, Demonstrations and Evaluation Programs were largely dedicated in FY 1982 to assembling information that could be used to attack spiralling hospital and Medicare Part A costs. In PL 97-35 (OBRA), Congress directed the Secretary to develop a model prospective payment system which States might use as an alternative to retrospective cost reimbursement.

In 1982, Yale University completed its development of "Diagnosis Related Groups (DRGs) Based Upon ICD-9-CM." This project provided a case-mix measurement tool which would be used in the implementation of TEFRA's Medicare Hospital Reimbursement reform which changed the Medicare unit of payment for routine inpatient care costs to a total operating costs per discharge, as opposed to per day. This revised system was also implemented by the state of New Jersey for its Hospital Cost Control Mechanism. Substantial amounts of intramural analyses were devoted to methods for establishing DRG cost-weights for measuring Medicare case-mix.

HCFA's Office of Research and Demonstrations developed the Secretary's Report to Congress on Prospective Payment Systems for Hospital Care which was delivered to Congress in the fall of 1982. Besides providing a useful technical guide for States considering the implementation of their own prospective payment programs, these analyses also contributed to formulation of the options for a Medicare prospective payment program, which the TEFRA legislation requested be reported to Congress by December 31, 1982.

A special single-theme issue of the Health Care Financing Review was prepared for December 1982. The theme was prospective payment, and the five research articles included presented results from individual States' reimbursement programs.

In FY 1982, HCFA participated in six hospital demonstration programs through Medicare and/or Medicaid waivers of standard Medicare-Medicaid reimbursement principles. Both Medicare and Medicaid waivers are in effect statewide in Maryland. The Maryland demonstration is expected to provide information on the long term effects of an all-payor State rate setting program on the rate of increase in hospital cost and the financial position of hospitals. In New Jersey, both Medicare and Medicaid are participating in the demonstration of a diagnosis specific hospital payment system, based on diagnosis-related groups (DRGs). All New Jersey hospitals are under this statewide demonstration. Medicare and Medicaid principles have been waived in Rochester and Finger Lakes areas of New York to allow the testing of two voluntary programs. These projects will help determine whether an areawide budget system will be effective in controlling hospital costs and whether local decisionmaking can effectively allocate financial resources between hospitals to cover the cost of new services.

In 1982, HCFA agreed to join statewide hospital demonstrations in the States of Massachusetts and New York. In Massachusetts, Medicare and Medicaid payments are based upon the Massachusetts Blue Cross method of hospital payment which controls each hospital's rate of increase in total revenues. Each hospital is expected to achieve "productivity" gains each year. In New York, the 3-year project is a test of a prospective per diem payment system for all payers in the State. Such system is based on the 1981 inpatient allowable cost trended forward to the current year.

Outpatient

Research projects continued through grants to Brandeis University and the American Hospital Association to gather and analyze hospital outpatient department cost and performance. A contract was awarded Mandex, Inc. to identify those services which were commonly performed both in physician offices and hospital outpatient departments. The eventual goal is an ambulatory care payment system that complements the hospital inpatient care payment system.

Data Development and Analyses

Contracts were also continued with the American Hospital Association to obtain hospital services and financial information, with Applied Management Sciences for statistical and analytic support of intramural hospital reimbursement studies, and with the Commission on Professional and Hospital Activities to obtain further analyses of hospital case-mix characteristics. A grant to Blue Cross of Western Pennsylvania for development of Patient Management categories for hospital case-mix and cost analyses was also continued, as was a grant to Johns Hopkins University for studies of severity of hospital illnesses.

Foreign Systems

A grant to the Brookings Institute for a study of "Allocation of Resources under the Budget Constraints Imposed by the British National Health System" was extended to enable the investigators to develop their report into a full-length book.

A grant to Columbia University "Paying the Hospital: Foreign Lessons for the United States" was completed. The investigation reports covered France, Holland, Switzerland, Canada, Great Britain and West Germany and found: (1) standardization in payment procedures and budgeting procedures lead to uniform reporting to payers and public authorities; (2) costs are the basis for paying non-profit and public hospitals except in countries using top-downward global budgeting; and (3) payment rules, units of payment and definitions of allowable costs are generally identical for all payers.

4. Industrial Organization

In September 1982, a contract was awarded to the Orkand Corporation for "Reexamination of the 44 Free-standing Emergency Centers or Emergicenters." This project attempted to contact and survey 44 emergicenters identified in a 1979 study for the Robert Wood Johnson Foundation, and attempted to identify newly formed centers. Analysis of center characteristics suggested that most such centers primarily deliver general medical care rather than specialize in care for trauma.

The Stanford Research Institute International contract for "Medigap, Study of Comparative Effectiveness of State Regulations" was continued. In 1982, a consumer survey was completed and an industry survey was designed. Also, an actuarial methodology for evaluating health insurance policies was developed.

5. Integrated Data Management Systems

HCFA supported the development and testing of uniform systems to collect and process billing and discharge data from hospitals and other institutions participating in Medicare and Medicaid. Uniform data systems could improve the Federal program capacity to reimburse for services in a manner that encourages efficient delivery at the same time that it improves the capacity to detect fraud, abuse, and error. The systems could also help eliminate paper transactions by using automated processes and will improve dissemination of data to multiple Federal, State and local users. In FY 82, most of HCFA's efforts to develop model integrated data management systems to collect, process and merge uniform discharge and billing data from hospitals entered their final period.

6. Long Term Care Research and Demonstration Activities--Overview

Total spending for nursing home care in the United States rose from $4.7 billion in calendar year 1970 to $20.6 billion in 1980 and $27.3 billion in 1982 (Health Care Financing Review, Fall 1983). This represents an average annual rate of increase of 15.8 percent. Of these amounts:

- Medicare spent approximately $0.3 billion in 1970, accounting for 5.6 percent of total nursing home expenditures. This increased to approximately $0.5 billion in 1982, accounting for approximately 1.8 percent of total nursing home spending.

- Medicaid (State and Federal) spent $1.4 billion on nursing homes in 1970 accounting for 29.8 percent of the total nursing home expenditures. In 1982, this increased to $13.2 billion in 1982, accounting for 48.4 percent of total nursing home spending in that year.

- Together, Medicare and Medicaid accounted for 50.2 percent of all spending for nursing home care in 1982.

- Medicare spent approximately $82 million on home health services in 1970. This rose to $1.3 billion in 1982, an average annual rate of increase of 26 percent.

- Medicaid spent approximately $17 million on home health care in 1970. This rose to $496 million in 1982, an average annual rate of increase of 33 percent.

HCFA's Office of Research and Demonstrations (ORD) conducts a program of research, demonstrations and evaluations in long term care, particularly as long term care relates to the populations and services covered by Medicare. In general, HCFA's long term care research activities involve the use and analysis of existing data, either collected by survey or abstracted from other data sources. Long term care research has focused primarily on describing and explaining the demand for long term care and the basic economic underpinnings of the long term care industry. In addition, considerable effort has been given to the development of a methodology to measure the quality of long term care provided in different settings. The purpose of this research is to develop an understanding of long term health care delivery, reimbursement and financing systems in order to provide some direction for private and public policymaking and to identify promising areas for demonstration activities.

ORD's long term care demonstration require the development of a rigorous research design and, within the design, a specific intervention is introduced into a live situation with subsequent observation of the outcomes. The evaluation findings, regarding the outcomes observed in our demonstrations, form the basis for future policy recommendations regarding the Medicare program.

Overview of Long Term Care Research

The role of the ORD long term care research program is to provide vital information relating to current and anticipated policy issues related to the goals of the Department of Health and Human Services. Most critical are those areas which will provide information about how to contain costs while increasing the efficiency and rationality of the long term care system. The research program includes congressionally mandated studies and research on fundamental issues which underlie a multiplicity of current and prospective policy questions.

HCFA's long term care research program consists of both intramural and extramural dimensions, which are intended to be complementary. On the intramural research side, for example, we have recently reviewed several major issues of direct and basic importance to the long term care system in the United States. The results of this study have recently been compiled and produced in a book entitled Long Term Care: Some Perspectives from Research and Demonstrations.

Our extramural research program is similarly oriented to provide policymakers the necessary data for enhancing policy formulation and program development. Three project areas are discussed below:

- o Determinants of Demand for Long Term Care;
- o Policy Effects on Long Term Care Utilization and Costs;
- o Nursing Home Costs, Quality and Reimbursement.

Determinants of Demand for Long Term Care

Research activities are being supported to explore determinants of the demand for long term care services. Studies in this group include research on: (1) the demographic and epidemiological factors affecting long term care, and (2) interrelationships among the elderly, their families and other informal supports and demand for long term care services.

In the first area, Duke University is studying the health status of the U.S. population using a model of the national history of important chronic diseases. With more accurate estimates of the prevalence and incidence of chronic diseases, better estimates of health care costs, particularly those for long term care services, can be derived.

In the second area, projects are investigating the interrelationships among the elderly, their families and demand for long term care services. A study by Hunter College is examining the family care-giving systems of the frail elderly. It will identify factors that strengthen or weaken the family system in providing care to the elderly and recommend methods of enhancing the family care-giving system which would sustain the elderly in the community and avoid more costly alternatives.

A study being conducted by the Community Service Society is examining the effects of providing substantial ongoing home service programs to functionally disabled low income adults. This study will be completed by mid-1982.

Policy Effects on Long-Term Care Utilization and Costs

Research activities are being supported to clarify the relationships between policies and the utilization and costs of long term care. Included among these are studies directed toward developing a better understanding of the components of costs for long term care for the purpose of enhancing future policy deliberations.

One study in this group is examining the behavior of physicians in long term care. Conducted by the Center for Health Economics Research, it will analyze the factors that influence physician willingness to make nursing home visits. In particular the study will examine the respective roles of Medicare reimbursement rates and Medicare disallowances on physician long term practices. This project's results will be available in mid-1983.

In another group of studies, two grantees, the University of Colorado and Yale University, will examine the relationship of case mix, quality and costs of nursing home care. The Colorado study is in the final of 3 years and conclusions from findings will be available later in 1982. Preliminary findings from this study indicate that groups of diagnoses and long term care problems cluster together by facility, suggesting that there are very likely specific facility groupings which emphasize care for similar types of patients. This study has found that residents of hospital-based facilities are generally older and more functionally dependent than residents of free-standing facilities. The Yale study is a 1-year project whose objective is to develop a patient classification typology according to resource utilization groups. Final results from this project will be available in late 1982. In addition to the broad utility of the results of the Colorado and Yale studies in enhancing our understanding of the generic relationships between case mix, cost and quality in nursing homes, they will be directly applicable to specific policy related analyses, as discussed under Section III.

On the basis of the findings from the nursing home survey and the data collection instruments derived for it, the University of Colorado is conducting a second study. In this 4-year project, it will evaluate nursing home and home health care providers in both free-standing and hospital-based settings. Both cost and quality of care will be assessed under four organizational arrangements.

Nursing Home Costs, Quality and Reimbursement

Research in this area has focused on the following issues: (1) the determinants of nursing homes' costs, (2) the effect of State regulations on the supply of nursing home beds, and (3) the effect of reimbursement methods on homes' willingness to admit "costly" patients.

This research has shown that in order to make valid cost comparisons among nursing homes, it is necessary to be able to compare the types of patients they treat (case mix) and the quality of care they provide. Research on two policy issues is discussed in greater detail.

Cost Limits for Skilled Nursing Facilities

Currently Medicare has set higher cost limits for hospital-based than for free-standing skilled nursing facilities. Are the large cost differences that we observe between these two types of facilities justified by differences in the costliness of their case mixes? Or do hospital-based facilities just employ a more expensive mix of personnel to treat similar patients? The University of Colorado (Grant No. 18-P-97145) and Yale University (Grant No. 18-P-97757) (described earlier) are investigating alternative approaches to case mix measurement that will hopefully be useful in explaining differences in nursing homes' costs.

Another University of Colorado grant (18-P-97712) will apply the measures developed in Grant No. 97145 specifically to the question of hospital-based versus free-standing facilities costs. (This grant will also compare the cost effectiveness of hospital-based and free-standing facilities in providing nursing home and home health care.) Preliminary results from this grant will be available by December 1983. The final report is due in February 1985.

Dual Participation by Skilled Nursing Facilities

Skilled nursing facility services are provided under both the Medicare and Medicaid programs. In 1980 Congress asked us to investigate why only two-thirds of the skilled facilities that participate in Medicaid also participate in Medicare. In particular, we were asked to study the impact of laws and regulations in discouraging facilities' participation in both programs and to assess the desirability of requiring dual participation. Research for much of the report was conducted by the Urban Institute under Grant No. 18-P-97727.

The research found that many States provide broader, longer term Medicaid benefits than does Medicare. Medicare covers only a small part of the nursing home population for very short term convalescent care. Administrative differences between the programs, especially in reimbursement methods, also discourage facilities' participation in Medicare. The report, delivered to Congress in July 1982, attempts to both acknowledge the critical differences between the programs and to suggest ways to make them more compatible where that is feasible.

Long Term Care (LTC) Services of Functionally Limited Elderly Persons

This survey will provide a nationally representative LTC data base that is necessary for future planning and policymaking in a nation becoming increasingly more elderly. This survey will supplement the Department's Channeling Demonstration Program in order that projections of costs and the feasibility of proposed national programs can be made at the end of the demonstration period. The first stage of this survey, limited to persons living in private households in the community, was conducted in 1982 from a list of persons selected from the Medicare enrollment files and screen for functional limitations. The second stage in 1984 will capitalize on the data collected in 1982 by revisiting those persons included in the previous survey no matter where they reside, in the community or in an institution. Data from the 1982 survey are currently being analyzed. Data from the 1984 survey will be used to make estimates on the transition probabilities of movements from the community to institutions. Data from the 1984 survey will be available in late 1986.

HCFA also conducts demonstrations in long term care for the growing numbers of the elderly, disabled and chronically ill. In FY 82, this program area encompassed studies of the populations in need of care, the factors affecting choice on different kinds of care, the effects of changes in public funding of services outside institutions, the economics of the long term care industry, and methods to reimburse nursing homes prospectively. HCFA also funded demonstrations of community systems that help elderly clients obtain services, and monitor the appropriateness of services.

During FY 81, the Department of Health and Human Services' National Channeling Demonstration, sponsored by the Office of the Assistant Secretary for Planning and Evaluation, the Administration on Aging, and HCFA, developed operational plans to implement the demonstration to test the effect of comprehensive assessment and case management on reducing nursing home and other institutional placement, controlling long term care costs and improving client outcomes. This demonstration is designed to investigate two channeling models: 1) a single entry community-based system of case management and assessment using existing health and social services (basic model) and 2) a single entry community-based system of case management and assessment with an expanded array of services to be reimbursed by the Medicare/Medicaid programs (complex model). During February through June 1982, the 10 demonstration sites began operations. In addition to case management and assessment services, the five basic model sites, which are located in Maine, Maryland, Kentucky, Texas and New Jersey, are authorized to pay for a limited amount of gap-filling services. Funds for additional noncovered Medicare and Medicaid services by the complex model sites come from a pooling of State and Federal monies based on a budget fixed at 60 percent of the costs that might be incurred if the demonstration population were treated in a nursing home. The complex model sites are located in New York, Massachusetts, Pennsylvania, Florida and Ohio.

On October 1, 1980, HCFA implemented a 2-year Medicare/Medicaid Hospice Demonstration project to gather data on the cost, use, and quality of care provided by hospice organizations to the terminally ill and their families. This project was developed to help define the scope of Federal involvement in the growing hospice movement. The 26 hospices selected to participate in this study are reimbursed for a number of items and services not currently covered by Medicare and Medicaid. Examples include: outpatient prescription drugs (currently covered by Medicaid), institutional respite and home respite services (primary care giver relief), visits by dieticians and homemakers, supportive and counseling visits to hospice patients during occasional hospital stays, continuous care (by nurses, home health aides, or homemakers) on a shift basis in the home, certain self-help devices, inpatient hospice care, and bereavement services to family members.

By the end of the second year of the demonstration (September 1982), Congress passed legislation authorizing the payment under Medicare of hospice services. Several aspects of the demonstration were incorporated into the hospice legislation, such as continuous care, respite care and patient/family counseling. It is anticipated that demonstration data on cost and use of hospice care will be used to draft the reimbursement and coverage regulations.

Section 966 of Public Law 96-499 authorized the Secretary to enter into agreements with States for the purpose of conducting demonstration projects for the training and employment of AFDC recipients as homemakers and home health aides and to provide these services to elderly and disabled persons at risk of institutional care. In June 1981, the Administrator of HCFA wrote to the Governor of the 49 States that have Medicaid programs and to the Mayor of the District of Columbia and invited them to apply for participation in the demonstration. Fourteen States submitted proposals, and in December 1981, HCFA sent to the seven selected States written confirmation of their participation in the project. The seven States are Arkansas, Kentucky, New Jersey, New York, Ohio, South Carolina and Texas.

As specified by the legislation, the demonstration will have a 6-month developmental period, up to 4 years of operation, and a 6-month phase-out period. Costs associated with the demonstration, including the training and employment (up to 12 months) of the AFDC recipients, will be paid with 90 percent Federal funding under Title XIX of the Social Security Act.

7. Physician Reimbursement

In consideration of the interest in further experimentation with competitive health care financing and delivery approaches which combine physician and hospital reimbursement, no new physician payment research grants or contracts were awarded in FY 1982. However, support for a number of projects was continued.

The major physician reimbursement research contracts continued in 1982 were the Health Economics Research study of alternative methods of packaging physician services for reporting or reimbursement including a spectrum from a services per visit day to annual capitation, and a contract to the Urban Institute for studies of alternative methods for developing relative value scales for physician services. In the latter, the approaches being examined include charge-based, statistical cost-function, time-based, micro-costing, and group decisionmaking (Delphi methods).

Grants to Princeton University for a study of Canadian and European physician fee schedule reimbursement systems and to Blue Cross/Blue Shield of Michigan for analyses of physician service utilization by market area were continued. A contract to the Institute for Demographic and Economic Studies for analysis of "Physician Earnings and Returns to Medical Training and Specialization" was continued, as was a contract to Pennsylvania Blue Shield for a study of "Pricing Behavior of Pennsylvania Physicians Since 1970."

Intramural research work was also dedicated to supporting several physician payment legislative implementation and regulation issues including the development of "A Methodology for Estimating the Full Time Equivalent Net Incomes for Physician Specialties," a staff work paper by James Cantwell and William Sobaski developed for the Bureau of Eligibility, Reimbursement, and Coverage. Another special study examined intra-State variations in the incidence of assistance at surgery. A work group was initiated involving most HCFA components to consider how the Medicare central statistical data might be modified to permit studies of specific procedures and specific types of medical practitioners and their program participation and behavior.

A compendium of data on physician services for 1975 through 1978 showing trends in physicians' charges and reimbursement by State, as well as reimbursement per beneficiary is being prepared. This compendium also shows data on assignment rates and the relative impact on beneficiary liability from unassigned claims, from the Part B deductible, from coinsurance requirements and from the Part B premium.

8. Program Evaluation

During FY 82, ORD was responsible for assessing the effectiveness of specific national programs or policies. Major evaluations are mandated by Congress, initiated by the Secretary, or determined by administrative initiative. During FY 82 the Office of Research and Demonstrations was responsible for three congressionally mandated studies: (1) the Hospital Providers of Extended Care Services (Rural Swing-Bed) Evaluation; (2) the Voluntary Certification of Medicare Supplemental Health Insurance Policies (Medigap certification/penalties) Evaluation; and (3) End-Stage Renal Disease evaluative studies. Administrative initiatives are in progress for estimation of inappropriate hospital utilization. In addition, ORD, in conjunction with Assistant Secretary for Planning and Evaluation, completed a study to further the development of an evaluation plan for the Medicaid program.

Swing-Bed

Congress mandated an evaluation of the impact of the rural swing-bed program. The evaluation will include analyses of the program's impact on access to and use of long term care services in rural areas with shortages of nursing home beds. It will assess whether such services furnished in small (less than 50 beds) rural hospitals are cost effective and comparable in quality to the services furnished in certified nursing home facilities. The report's findings will assist in determining whether eligibility to participate in the swing-bed program should be extended to other hospitals, regardless of bed size or geographic location, when there is a shortage of long term care beds. Findings consistent with earlier demonstration experiences would validate expectations that the swing-bed program could assist rural communities in meeting both long term care and acute care needs.

Medigap

ORD recently funded a congressionally mandated study of the possible "Medigap" problem. The purpose of this study is to ascertain the effectiveness of State insurance regulations, permitting more informed choice, reducing duplicative coverage, and limiting marketing abuses. A survey of Medicare beneficiaries and of insurance companies is being conducted in six States: California, Florida, Mississippi, New Jersey, Washington, and Wisconsin. A Medigap Advisory Panel was formed with 10 representatives from State and Federal regulatory authorities, the insurance industry and consumer and aging organizations. The panel met to review the consumer survey design. A consumer survey pretest was conducted in the Denver area in winter 1982. Data collection for the consumer survey was begun in April 1982.

The Medigap legislation further requires ongoing evaluations of the effect of the certification and criminal penalties provisions. A descriptive report on the Medigap certification process is included as a separate section of this report. Subsequent biennial Medigap evaluation reports will include analyses of the impact of the program and penalties on the type, market share, value, and cost to individuals entitled to benefits of Medigap policies certified by the Secretary.

End-Stage Renal Disease

ORD has a broad-ranging research, demonstration and evaluation program in the area of End-Stage Renal Disease (ESRD). Information about these activities is included in the detailed ESRD section of this report.

Inappropriate Hospital Utilization

Administrative initiatives are underway that will allow the Secretary to determine the medical necessity of inpatient hospital care and to make regional and national estimates of inappropriate hospital utilization. There are two medical review methodologies being studied for this purpose: (1) the Appropriateness Evaluation protocol; and (2) the Standardized Medreview Instrument. The Appropriateness Evaluation Protocol (AEP) developed at Boston University is currently available. The AEP is an instrument for determining appropriateness of hospital use. It is based on objective criteria items related to patient medical services, nursing and life support services, and patient condition. In addition, it contains a list of reasons for inappropriateness, structured to assist in identifying the causes of unnecessary admissions and days of care. The developers of the AEP have tested it and believe it to be a reliable and valid instrument that can be easily and economically applied in chart reviews by utilization review coordinators. (Gertman, P.M., and Restuccia, J.D., "The Appropriateness Evaluation protocol: A Technique for Assessing Unnecessary Days of Hospital Care" Medical Care, 19:855-871, 1981).

Using the AEP instrument, these researchers compared inappropriate hospital use in four regions of the country. The study objectives were threefold: (1) to measure the amount of inappropriate (i.e., medically unnecessary) hospital admissions and days of care, (2) to identify the patient, hospital and seasonal factors associated with inappropriate hospital use, and (3) to identify reasons for hospitalization in patients judged to be inappropriately hospitalized. AEP was retrospectively applied by trained nurse reviewers to a sample of 4,800 patient records to assess the appropriateness of hospital admissions and days of care. Preliminary results indicate a substantial amount of inappropriateness as well as striking variations in the rates of inappropriateness for both hospital admissions and days of care. Overall, they found that the level of inappropriate admissions for Federal beneficiaries was 21 percent and the regional variation ranged from 13 percent to 31 percent. Cases judged to have inappropriate admissions were excluded from analyses of the factors associated with inappropriate days.

The other methodology being studied is the Standardized Medreview Instrument (SMI) which is intended to be a state of the art medical review protocol that integrates the best of all major medical utilization review techniques. Following an extensive pretest of the instrument in 1981 in cooperation with the American Hospital Association (AHA) and an expert Technical Advisory Panel (TAP), a study of acute care hospitals involving primary data collection from 253 hospitals using (national) probability sampling techniques was conducted for the year 1981. The preliminary data analysis suggests a significantly lower rates of inappropriate admissions (on the order of 5-10%) than was found in earlier studies. The study population includes all acute care non-Federal hospitals, in the continental U.S. Excluded were specialty hospitals, normal deliveries and pediatric patients. The final national estimates of non-acute utilization will be available in 1983. This study is unique in that it will provide reliable estimates of the problem for the first time and will include all classes of payors, (commercial insurors, Blue Cross, self pay, and workmen's compensation) as opposed to merely Medicare and Medicaid patients usually studied and reported.

9. Quality and Effectiveness

A "National Heart Transplantation Study" is being carried out by the Battelle Human Affairs Research Center in Seattle. This project has been designed to evaluate the scientific, economic, ethical, legal, and social factors related to heart transplantation. It will include the collection and analysis of data on organ procurement, need for transplantation, costs, and survival of transplant patients. This project began in September of 1981 and data collection was underway in FY 1982.

An Evaluation of Part B Fixed-Price Contracts is being conducted by Abt Associates. This project is designed to evaluate the Medicaid Part B fixed-price carrier experiments in Maine, Illinois, and Upstate New York. The purpose of the study is to determine whether the fixed-price method will reduce Federal program costs through more efficient processing, while maintaining quality of carrier performance.

Data Base and Statistical Activities

The central administration of the Medicare program at the Federal level has permitted the development of a uniform multipurpose Medicare data base that serves the needs of planners, researchers and policymakers. HCFA uses this claims based statistical system, together with other reporting systems, to prepare a wide variety of statistical and analytical reports and studies on the utilization and reimbursement of health care services financed by Medicare and Medicaid.

HCFA maintains a statistical program to generate information on the ongoing operation of the Medicare and Medicaid programs. Program statistic reports are issued on a regular basis that provide data on the number and characteristics of program beneficiaries; the number, distribution, and characteristics of providers certified to furnish services to Medicare beneficiaries; and the patterns of use of program benefits by beneficiaries. Use of benefits is examined by the characteristics of the persons using them, the providers furnishing the services, and the distribution of charges and reimbursements to beneficiaries and providers. The purpose of these reports is to show trends and to examine the factors that may be influencing those trends.

A major new annual statistical report by HCFA was designed and published in 1982, the Medicare and Medicaid Data Book 1981, to present comprehensive program data describing the Medicare and Medicaid programs. This annual book is intended as a resource tool for public officials, researchers, policy analysts, and consumers with an interest in these health programs. It features analyses on recent trends in program beneficiaries, expenditures, and service utilization, as well as in-depth discussions of the basic operating principles of each program.

Other ongoing statistical studies are undertaken to better understand access and use of Medicare services. This includes selected highlight notes which provide a brief and timely summary on the use and cost of services for each of the major Medicare program benefits; e.g., short-stay and long-stay hospital, skilled nursing care, home health agency, hospital outpatient, etc.

Statistical studies are also undertaken to examine areas of special interest in regard to policy and legislative initiatives. For examples, studies on the distribution of Medicare expenditures by survival status, and the composition of Medicare short-stay hospital charges provided the following relevant highlights:

- o Medicare enrollees who died in 1979 accounted for about 5 percent of all aged persons eligible for benefits, but they received close to 21 percent of total Medicare reimbursements in 1979.
- o Ancillary services for Medicare beneficiaries discharged from short-stay hospitals during 1979 accounted for about 51 percent of the total Hospital Issuance (HI) short-stay hospital charges.

A HCFA program statistics report on the availability and access to Medicare providers and suppliers of services showed the following significant variation by geographic area:

- o The number of Medicare certified short-stay hospital beds per 1,000 HI enrollees ranged from 31 in the New England States to 42 in the West South Central States. Certified skilled nursing facility beds per 1,000 HI enrollees ranged from 2 in the West South Central States to 28 in the Pacific States.
- o Among the 50 States, 19 had more than 100 HHA's and 9 States, including the District of Columbia, had 15 or fewer agencies approved by Medicare.
- o Of the independent laboratories certified by Medicare, 33 percent of them were located in California, Texas, and New York.

A new data base that was fully implemented in FY 80 is derived from the Medicare statistical system. This data base links the Medicare Eligibility files with the Part A and Part B claims files for a 5% sample of all Medicare beneficiaries. This file is called "the Continuous History Sample" and captures beneficiary service information from 1974 on.

Work is also beginning on projects to link this new continuous history sample to other data bases outside HCFA to expand the range of analyses possible on Medicare beneficiaries. The Medicare history file will be linked to mortality data from the National Center for Health Statistics and to disability award data from the Social Security Administration. These linked files will permit studies of the relation of Medicare use to mortality and disability variables.

In addition to reports based on the Medicare and Medicaid claims payment systems, HCFA has planned a series of reports from the National Medical Care Utilization and Expenditure Survey (NMCUES) of 1980. NMCUES collected detailed sociodemographic, health status, health insurance, and health care payment data that were not available from either the Medicare or Medicaid administrative record systems. The data will allow for analysis of policy issues relating to out-of-pocket costs, access to health care, and Medicaid use by social and ethnic groups.

Two reports on aged Medicare beneficiaries, concerning their health status and access to medical care, will be among the early reports prepared. Publication of the NMCUES questionnaires and accompanying procedures is expected in early 1983.

In addition to reports on HCFA programs, ORD maintains a data base on national health spending by sector of care, and by source of payment. The Fall 1983 issue of the Health Care Financing Review reported trends in spending and sources of payment through calendar year 1982. The article reported that national health care spending reached $322.4 billion in 1982, up 12.5 percent from 1981, and comprised 10.5 percent of the Gross National Product. Medicare and Medicaid provided $86 billion, or more than a quarter of total health spending.

Projections of national health spending by sector and by source of payment through 1990 appeared in the March 1983 issue of the Health Care Financing Review. The article projected that National Health Expenditures would reach $756 billion in 1990, or 12.0 percent of the Gross National Product, primarily due to increased spending for hospital and nursing home care. The national health expenditure data base also includes distribution of health spending and sources of payment by age group, with special emphasis on persons age 65 and older.

APPENDIX A

Part A Intermediaries and Part A Blue Cross Plans

PART A - INTERMEDIARIES

Blue Cross Association
676 North St. Clair Street
Chicago, IL. 60611

Aetna Life Insurance Company
151 Farmington Avenue
Hartford, CT 06156

Cooperative de Seguros
de Vida Puerto Rico
Post Office Box 3428 G.P.O.
San Juan, PR 00936

Hawaii Medical Service Association
1504 Kapiolani Boulevard
Post Office Box 860
Honolulu, HI 96808

Kaiser Foundation Health Plan, Inc.
1956 Webster Street
Room 310-A
Oakland, CA 94612

Mutual of Omaha Insurance Company
Post Office Box 456
Downtown Station
Omaha, NE 68101

Nationwide Mutual Insurance Company
Post Office Box 1625
Columbus, OH 43216

The Prudential Insurance Company
of America
Drawer 471
Millville, NJ 08332

The Travelers Insurance Company
One Tower Square
Hartford, CT 06115

PART A - BLUE CROSS PLANS

Blue Cross and Blue Shield
of Arizona, Inc.
321 West Indian School Road
Post Office Box 13466
Phoenix, AZ. 85002

Arkansas Blue Cross and Blue
Shield, Inc.
601 Gaines Street
Little Rock, AR 72203

Blue Cross of Southern California
Post Office Box 70000
Van Nuys, CA 91470

Blue Cross of Northern California
1950 Franklin Street
Oakland, CA 94659

Blue Cross and Blue Shield
of Colorado
700 Broadway
Denver, CO 80273

Blue Cross and Blue Shield
of Connecticut, Inc.
370 Bassett Road
North Haven, CT 06473

Blue Cross and Blue Shield
of Delaware, Inc.
201 West 14th Street
Wilmington, DE 19899

Group Hospitalization, Inc.
550 12th Street, SW
Washington, DC 20024

Blue Cross of Florida, Inc.
Post Office Box 1798
Jacksonville, FL 32201

PART A - BLUE CROSS PLANS

Blue Cross and Blue Shield
of Georgia/Atlanta, Inc.
3348 Peachtree Road, NE
Post Office Box 4445
Atlanta, GA 30302

Blue Cross of Georgia/Columbus, Inc.
2357 Warm Springs Road
Post Office Box 7368
Columbus, GA 31908

Blue Cross of Idaho Health
Service, Inc.
1501 Federal Way
Post Office Box 7408
Boise, ID 83707

Health Care Service Corporation
233 North Michigan Avenue
Chicago, IL 60601

Mutual Hospital Insurance, Inc.
120 West Market Street
Indianapolis, IN 46204

Blue Cross of Iowa
Ruan Building
636 Grand Avenue
Des Moines, IA 50307

Blue Cross of Western Iowa
and South Dakota
Third and Pierce Streets
Sioux City, IA 51102

Blue Cross of Kansas, Inc.
1133 Topeka Boulevard
Post Office Box 239
Topeka, KS 66601

Blue Cross and Blue Shield
of Kentucky, Inc.
9901 Linn Station
Louisville, KY 40223

Louisiana Health Service
and Indemnity Company
Post Office Box 15699
Baton Rouge, LA 70895

Associated Hospital Service
of Maine
110 Free Street
Portland, ME 04101

Blue Cross of Maryland,Inc.
700 East Joppa Road
Towson, MD 21204

Blue Cross of Massachusetts, Inc.
100 Summer Street
Boston, MA 02106

Blue Cross and Blue Shield
of Michigan
600 Lafayette East
Detroit, MI 48226

Blue Cross and Blue Shiel
of Minnesota
3535 Blue Cross Road
St. Paul, MN 55765

Blue Cross and Blue Shield
of Mississippi, Inc.
Post Office Bos 1043
Jackson, MS 39205

Blue Cross Hospital Service, Inc.
of Missouri
4444 Forest Park
St. Louis, MO 63108

Blue Cross of Montana
3360 10th Avenue, South
Post Office Box 5017
Great Falls, MT 59403

Blue Cross and Blue Shield
of Nebraska
Post Office Box 3248
Main Post Office Station
Omaha, NE 68103

New Hampshire-Vermont Health
Service
Two Pillsbury Street
Concord, NH 03306

Hospital Service Plan
of New Jersey
33 Washington Street
Newark, NJ 07102

PART A - BLUE CROSS PLANS

New Mexico Blue Cross
and Blue Shield, Inc.
12800 Indiana School Road, NE
Albuquerque, NM 87112

Blue Cross and Blue Shield
of Greater New York
622 Third Street
New York, New York 10017

Blue Cross and Blue Shield
of North Carolina
Post Office Box 2291
Durham, NC 27702

Blue Cross of North Dakota
4510 13th Avenue, SW
Fargo, ND 58121

Hospital Care Corporation
1351 William Howard Taft Road
Cincinnati, OH 45206

Blue Cross of Northeast Ohio
2066 East Ninth Street
Cleveland, OH 44115

Blue Cross of Central Ohio
255 East Main
Post Office Box 16526
Columbus, OH 43216

Blue Cross of Northwest Ohio
Post Office Box 943
Toledo, OH 43656

Blue Cross and Blue Shield
of Oklahoma
1215 South Boulder Avenue
Tulsa, OK 74119

Northwest Hospital Service
100 SW Market Street
Post Office Box 1217
Portland, OR 97201

Hospital Services Plan
of the Lehigh Valley
1221 Hamilton Street
Allentown, PA 18102

Capital Blue Cross
100 Pine Street
Harrisburg, PA 17101

Blue Cross of Greater Philadelphia
1333 Chestnut Street
Philadelphia, PA 19107

Blue Cross of Western Pennsylvania
One Smithfield Street
Pittsburgh, PA 15222

Hospital Service Association
of Northeastern Pennsylvania
Blue Cross Building
70 North Main Street
Wilkes-Barre, PA 18711

Blue Cross of Rhode Island
444 Westminster Mall
Providence, RI 02901

Blue Cross and Blue Shield
of South Carolina
Drawer F. Forest Acres Branch
Columbia, SC 29260

Blue Cross and Blue Shield
of Tennessee
Blue Cross Building
Chattanooga, TN 37402

Group Hospital Service, Inc.
Post Office Box 222146
Dallas, TX 75222

Blue Cross of Utah
2455 Parleys Way
Post Office Box 30270
Salt Lake City, UT 84125

Blue Cross of Virginia
2015 Staples Mill Road
Post Office Box 27401
Richmond, VA 23279

Blue Cross of Southwestern
Virginia
Post Office Box 13047
3959 Electric Road
Roanoke, VA 24045

Blue Cross of Washington
and Alaska, Inc.
15700 Dayton Avenue, Inc.
Post Office Box 327
Seattle, WA 98111

Blue Cross Hospital Service, Inc.
Post Office Box 1353
Commerce Square
Charleston, WV 25325

Parkersburg Hospital Service, Inc.
Post Office Box 1948
Parkersburg, WV 26101

Associated Hospital Service, inc.
401 West Michigan Street
Post Office Box 2025
Milwaukee, WI 53203

Blue Cross Blue Shield
of Wyoming
4000 House Avenue
Post Office Box 2266
Cheyenne, WY 82001

APPENDIX B

Part B - Blue Shield Plans

Part B - Commercials, Other

PART B - BLUE SHIELD PLANS

Blue Cross and Blue Shield
of Alabama
450 Riverchase Parkway, East
Birmingham, AL 35298

Arkansas Blue Cross and
Blue Shield, Inc.
601 Gaines Street
Little Rock, AK 72203

California Physicians Service
2 Northpoint Street
Post Office Box 7968-Rincon Annex
San Francisco, CA 94120

Blue Cross and Blue Shield
of Colorado
700 Broadway
Denver, CO 80273

Blue Shield of Florida, Inc.
Post Office Box 1798
Jacksonville, FL 32231

Mutual Medical Insurance, Inc.
120 West Market Street
Indianapolis, IN 46204

Blue Shield of Iowa
Ruan Building
636 Grand Avenue
Des Moines, IA 50307

Blue Shield of Kansas, Inc.
113 Topeka Boulevard
Post office Box 239
Topeka, KS 66601

Blue Shield of Maryland, Inc.
700 East Joppa Road
Towson, MD 21204

Blue Shield of Massachusetts, inc.
100 Summer Sreet
Boston, MA 02106

Blue Cross and Blue Shield
of Michigan
600 Lafayette East
Detroit, MI 48226

Blue Shield of Kansas City
Post Office Box 169
Kansas City, MO 64141

Montana Physicians Service
404 Fuller Avenue
Post Office Box 4310
Helena, MT 59601

New Hampshire-Vermont Health
Service
Two Pillsbury Street
Concord, NH 03306

Blue Shield of Western
New York, Inc.
15 Chenango Street
Binghamton,NY 13901

Blue Cross and Blue Shield
of Greater New York
622 Third Avenue
New York, NY 10017

Blue Shield of North Dakota
4510 13th Avenue, SW
Fargo, ND 58121

Pennsylvania Blue Shield
Post Office Box 65
Camp Hill, PA 17011

Seguros de Servicio de Salud
de Puerto Rico, Inc.
Post Office Box 3628 G.P.O.
San Juan, PR 00936

Blue Shield of Rhode Island
444 Westminster Mall
Providence, RI 02901

Blue Cross and Blue Shield
of South Carolina
Drawer F, Forest Acres Branch
Columbia, SC 29219

Group Medical and Surgical Service
Post Office Box 222147
Dallas, TX 75222

Blue Shield of Utah
2455 Parleys Way
Post Office Box 30270
Salt Lake City, UT 84125

Washington Physicians Service
2401 4th Avenue
4th and Battery Building
6th Floor
Seattle, WA 98121

Wisconsin Physicians Service
Insurance Corporation
Post Office box 9277
Madison, WI 53715

PART B - COMMERCIALS, OTHER

Aetna Life Insurance Company
151 Farmington Avenue
Hartford, CT 06156

Connecticut General Life
Insurance Company
900 Cottage Grove Road
Hartford, CT 06152

E.D.S. Federal Corporation
7171 Forest Lane
Dallas, TX 75230

The Equitable Life Assurance
Society of the United States
1285 Avenue of the Americas
New york, NY 10019

General American Life Insurance
Company
Post Office Box 505
St. Louis County, MO 63166

Group Health Incorporated
326 West 42nd Street
New York, NY 10036

Metropolitan Life Insurance Company
One Madison Avenue
New York, NY 10010

Mutual of Omaha Insurance
Company
Post Office Box 456
Downtown Station
Omaha, NE 68101

Nationwide Mutual Insurance Company
Post Office Box 1625
Columbus, OH 43216

Transamerica Occidental Life
Insurance Company
Post Office Box 54905, Terminal Annex
12th at Hill Street
Los Angeles, CA 90054

Pan-American Life Insurance
Company
Post Office Box 60450
New Orleans, LA 70160

The Prudential Insurance
Company of America
Drawer 471
Millville, NJ 08332

The Travelers Insurance Company
One Tower Square
Hartford, CT 06115

State Agency

Department of Human Services
Post Office Box 25352
State Capitol Station
Oklahoma City, OK 73125

APPENDIX C

MEDICARE: Enrollment[1] and Benefit Payments[2] by Residence of the Beneficiary
Fiscal Year 1982

	Enrollment		Benefit Payments (in millions)	
	Hospital Insurance	Medical Insurance	Hospital Insurance	Hospital Insurance
All Areas[3]	29,068,966	28,412,282	$34,343	$14,806
Alabama	496,637	493,740	563	202
Alaska	14,329	12,505	22	8
Arizona	353,458	345,421	345	200
Arkansas	349,425	346,166	310	156
California	2,679,155	2,669,342	3,744	2,012
Colorado	277,118	272,185	317	152
Connecticut	407,308	403,346	465	214
Delaware	69,639	68,308	74	38
District of Columbia	73,115	71,368	139	63
Florida	1,798,561	1,793,015	2,178	1,174
Georgia	598,471	597,580	575	269
Hawaii	86,944	85,662	87	49
Idaho	109,014	106,573	92	40
Illinois	1,369,600	1,354,430	1,970	642
Indiana	661,640	649,819	774	262
Iowa	422,336	417,340	447	149
Kansas	330,361	325,829	411	146
Kentucky	466,716	464,842	456	153
Louisiana	448,439	426,548	484	154
Maine	161,071	159,391	180	65
Maryland	436,928	426,939	619	256
Massachusetts	787,282	774,556	1,113	455
Michigan	1,062,213	1,050,683	1,466	682
Minnesota	524,859	518,977	569	209
Mississippi	324,370	323,703	320	119
Missouri	712,124	700,881	941	259
Montana	98,033	96,204	94	40
Nebraska	221,674	218,325	228	79
Nevada	81,849	80,042	119	57
New Hampshire	116,592	114,164	122	48
New Jersey	964,540	959,410	1,167	569
New Mexico	134,538	132,159	134	66
New York	2,347,101	2,325,243	2,973	1,416
North Carolina	704,593	699,740	643	260
North Dakota	89,100	87,723	110	38
Ohio	1,325,463	1,307,070	1,670	605
Oklahoma	401,086	396,372	447	158
Oregon	346,217	334,870	390	145
Pennsylvania	1,721,332	1,696,324	2,224	940
Rhode Island	141,194	139,090	164	80
South Carolina	341,903	338,205	315	127
South Dakota	99,804	98,063	105	34
Tennessee	587,275	584,642	610	226
Texas	1,480,352	1,473,530	1,772	803
Utah	124,425	119,254	104	50
Vermont	66,221	65,459	72	26
Virginia	578,375	565,325	596	249
Washington	489,461	479,014	462	220
West Virginia	277,826	275,080	288	92
Wisconsin	634,153	627,954	716	263
Wyoming	42,350	41,163	44	16
Puerto Rico	369,738	225,922	93	56
Virgin Islands	5,186	4,808	3	1
Guam and Other Areas	2,979	2,467	2	1

[1] Enrollment for HI and/or SMI as of July 1, 1982 based on residence of beneficiary (preliminary).

[2] Benefit payments represent vouchers of credit drawn by intermediaries and carriers during the period October 1, 1981 thorugh September 30, 1982, excluding administrative expenses. Distribution by region estimated based on interim reimbursements as reflected on bills recorded in central office. Payments reflect residence of the beneficiary.

[3] All areas total includes beneficiaries who live in foreign countries or have unknown residence. These beneficiaries are excluded from the individual region totals.

APPENDIX D

Five-Year Trend Analysis for Contractor Administrative Costs and Productivity Improvements

PART A INTERMEDIARIES

FY 1978 Through FY 1982

The following tables contain significant workload, administrative cost, average manpower, and benefit payment data reflecting the combined performance of all Part A intermediaries from Fiscal Year 1978 through 1982.

During this period, the annual workloads rose a total of 30.7 percent over the base, while total administrative costs rose only 21.3 percent. In terms of total unit cost, the decrease from $5.49 to $5.09 is 7.3 percent. These decreased costs reflect the expanded use of automatic data processing equipment, improved procedures, and the implementation of fixed price contracts.

PART A INTERMEDIARIES
TREND DATA AND INDICES
WORKLOAD AND COST

FY	Bills Processed	Total Adm. Cost	Total Unit Cost	Admin. Cost	Unit Cost Ex. Audit	Provider Audit and Reimbursement
78	34,862,400	$191,259,600	$5.68	$146,848,500	$4.57	$44,146,800
79	36,410,000	$201,546,200	$5.54	$147,411,000	$4.05	$51,980,900
80	39,789,300	$216,037,000	$5.43	$155,131,500	$3.90	$60,905,500
81	42,539,800	$234,615,400	$5.52	$166,190,200	$3.91	$68,425,300
82	45,551,700	$231,930,900	$5.09	$162,468,100	$3.57	$69,462,800

INDICES (FY 78 AS 100 PERCENT)

FY	Bills Processed	Total Adm. Cost	Total Unit Cost	Admin. Cost	Unit Cost Ex. Audit	Provider Audit and Reimbursement
78	100.0	100.0	100.0	100.0	100.0	100.0
79	104.4	105.4	100.9	103.9	99.5	109.1
80	114.1	113.0	98.9	109.4	95.8	127.8
81	122.0	122.7	100.5	117.2	96.1	143.6
82	130.7	121.3	92.7	114.6	87.7	145.8

PART A INTERMEDIARIES
TREND DATA AND INDICES
PRODUCTIVITY, PERSONAL SERVICE COSTS, AND BENEFITS

FY	Staff Years	Productivity Per Staff Year	Average PS Cost Per Staff year	Benefits Paid (M)	Benefits Paid Per Bill	Percent Administrative Cost to Beneficiary (Including Audit)
78	6,895.1	5,056	$14,415	$18,405,100	$527.93	1.0
79	6,681.0	5,450	$15,623	$20,931,400	$574.88	1.0
80	6,211.6	6,406	$17,121	$25,238,000	$634.29	0.9
81	5,819.5	6,862	$18,157	$30,703,700	$721.76	0.8
82	4,459.7	9,008	$21,263	$36.590,600	$803.28	0.6
			INDICES (FY 1978 AS 100 PERCENT)			
78	100.0	100.0	100.0	100.0	100.0	100.0
79	96.9	107.8	108.4	113.7	108.9	100.0
80	90.1	126.7	118.8	137.1	120.1	90.0
81	84.4	135.7	126.0	166.8	136.7	80.0
82	64.7	178.2	147.5	198.8	152.2	60.0

PART B CARRIERS

FY 1978 Through FY 1982

The following tables contain significant workload, administrative cost, average manpower, and benefit payment data reflecting the combined performance of all Part B carriers from fiscal year 1978 through 1982.

During the period, the annual workload rose a total of 54.2 percent over the base, while total administrative costs rose only 33.2 percent. In terms of unit cost for processing claims, the decrease from $2.86 to $2.47 is 13.1 percent. Contributing to the reduced cost of processing a claim, in addition to expanded use of data processing equipment and improved procedures, are the increased use of facilities management subcontracts and fixed price contracts.

PART B CARRIERS
TREND DATA AND INDICES

Workload and Cost

FY	Claims Processed	Administrative Cost	Claims Unit Cost	Payment Received Processed	Payment Received Unit Cost
78	120,439,700	$344,572,700	$2.86	100,087,300	$3.43
79	133,494,900	$375,273,500	$2.81	112,864,600	$3.32
80	152,312,600	$389,043,300	$2.61	129,465,800	$3.07
81	169,541,700	$450,537,700	$2.66	148,529,800	$3.03
82	185,769,600	$458,819,500	$2.47	158,994,200	$2.89

Indices

FY	Claims Processed	Administrative Cost	Claims Unit Cost	Payment Received Processed	Payment Received Unit Cost
78	100.0	100.0	100.0	100.0	100.0
79	110.8	108.9	98.3	112.8	96.8
80	126.5	115.5	91.3	129.4	89.5
81	140.8	130.8	93.0	148.4	88.3
82	154.2	133.2	86.4	158.9	84.3

PRODUCTIVITY, PERSONAL SERVICE COST, AND BENEFITS EXCLUDING PSRO AND HMO

FY	Staff Years	Productivity Per Staff Year	Average PS Cost Per Staff Year	Benefits Paid (M)	Benefits Paid Per Bill	Percent Administrative Cost to Beneficiary
78	16,851.8	7,110	$12,770	$5,436,781	$45.14	6.3
79	16,474.0	8,103	$13,753	$6,360,065	$47.64	5.9
80	15,514.9	9,817	$15,172	$7,798,407	$51.20	5.1
81	15,523.8	10,293	$16,601	$9,388,767	$55.38	4.8
82	13,202.9	13,247	$18,677	$11,186,164	$60.20	4.1

INDICES (FY 1978 AS 100 PERCENT)

FY	Staff Years	Productivity Per Staff Year	Average PS Cost Per Staff Year	Benefits Paid (M)	Benefits Paid Per Bill	Percent Administrative Cost to Beneficiary
78	100.0	100.0	100.0	100.0	100.0	100.0
79	97.8	114.0	107.7	117.0	105.5	93.6
80	92.1	138.1	118.8	143.4	113.4	81.0
81	92.1	144.8	130.0	142.7	122.7	76.2
82	78.3	186.3	146.3	205.7	133.4	65.1

APPENDIX E.

SIGNIFICANT LEGISLATION ENACTED IN FY 82

TAX EQUITY AND FISCAL RESPONSIBILITY ACT OF 1982 (P.L. 97-248)

On September 3, 1982, the President signed into law H.R. 4961, the "Tax Equity and Fiscal Responsibility Act of 1982." This new public law (P.L. 97-248) includes many provisions affecting the Medicare program. Summaries of changes having a direct impact on Medicare appear below.

1. Medicare Reimbursement to Hospitals (Section 101)

Prior Law: Medicare reimbursement for a hospital's inpatient routine operating costs (i.e., bed, board, and routine nursing) may not exceed 108 percent of the average routine cost per day incurred by other hospitals of the same type unless it qualifies for an exception or exemption.

Modifications:

223 Limits

- This provision extends Section 223 limits to include ancillary costs applied on a cost-per-case basis and adjusts each hospital's limit by a case mix adjustment. In no case would reimbursement on a cost-per-case basis be reduced below the allowable cost-per-case reimbursement for the hospital's cost reporting period that immediately precedes the first cost reporting period to which the new limitation is applicable. Limits are set at 120 percent of the mean in FY 1983, and reduced to 115 percent in FY 1984, and to 110 percent in FY 1985. The provision requires the Secretary to provide appropriate exemptions, exceptions and adjustments from the limits. Special adjustments are to be made for the needs of psychiatric hospitals and hospitals that incur additional costs in treating low income and Medicare patients. Non-SMSA hospitals with less than 50 beds on and after enactment are exempted from the limits.

  Effective Date: Cost reporting periods beginning on or after October 1, 1982.

Rate of Increase Limit

- The provision establishes a 3-year limit on a per case basis on the rate of increase in hospital revenue. The target rate is the previous year's allowable cost per case (or after the first year, the previous year's target amount) increased by the percentage increase in the hospital wage-and-price index, plus 1 percentage point. For the first 2 years, hospitals would be allowed 25 percent of those costs in excess of their rate of increase limit; none of the excess would be reimbursed in the third year. Hospitals with operating costs below the target rate of increase would be paid their costs plus a bonus of

50 percent of the savings (not to exceed 5 percent of the target rate). Provider payments could not exceed the amount payable under the new section 223 limitations. The Secretary would provide appropriate exemptions and adjustments to the target rate, specifically including an adjustment for psychiatric hospitals. The Secretary also is required to compute a reduction in payments to hospitals which withdraw their employees from the OASDHI program after August 15, 1982. The reduction would reflect the savings achieved through withdrawal, but can be offset by expenditures for comparable insurance benefits.

Effective Date: Limits apply to a hospital's first 3 cost reporting periods beginning on or after October 1, 1982, but cease upon implementation of a prospective payment system.

Prospective Reimbursement

- This provision requires the Secretary to develop, in consultation with the Senate Finance Committee and the House Ways and Means Committee, Medicare prospective reimbursement legislative proposals for hospitals, skilled nursing facilities and, to the extent feasible, other providers.

  Effective Date: A report to the Committees on the proposals is due by December 31, 1982.

Recognition of State Hospital Cost Control System

- Medicare hospital payments could be made (at the request of a State) under a hospital reimbursement control system in the State if, and so long as, (1) the system applies to substantially all non-Federal hospitals to at least 75 percent of hospital inpatient revenues in the State, and to the State's Medicaid program, (2) the system treats payors, hospital employees, and patients equitably, and (3) the Secretary is satisfied that the system will not result in greater Medicare expenditures over a 3-year period. In making this determination, the Secretary could recognize previous cost savings under the system. The provision also prohibits the Secretary from terminating Medicare hospital reimbursement demonstration projects in continuous operation since July 1, 1977, such as Maryland, until 6 months after he notifies the State of his decision to terminate.

2. Single Reimbursement Limit for Skilled Nursing Facilities and Home Health Agencies (Sections 102 and 105)

Prior Law: Regulations establish different reimbursement limits for skilled nursing facilities and home health agencies depending on whether they are hospital-based or freestanding facilities.

Modification: The provisions requires the Secretary to issue regulations establishing a single reimbursement limit for skilled nursing facilities and for home health agencies, based on the cost experience of freestanding facilities. Exceptions could be made based on legitimate differences in hospital-based skilled nursing facilities resulting from factors such as more complex case mix or the effects of Medicare cost allocation requirements.

Effective Date: The provision applies to home health agency reporting periods beginning on or after the date of enactment, and skilled nursing facility cost accounting periods beginning on or after October 1, 1982.

3. Elimination of Nursing Differential (Section 103)

Prior Law: Since 1969, Medicare has paid hospitals and skilled nursing facilities an additional amount for inpatient routine nursing salary costs on the theory that older patients require more nursing care than younger patients. The Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35) reduced, effective October 1, 1981, the hospital inpatient routine nursing salary cost differential from 8.5 to 5 percent.

Modification: The provision eliminates the routine nursing salary cost differential for both hospitals and skilled nursing facilities.

Effective Date: For cost reporting periods ending after September 30, 1982 but only for the portion of that period occurring after that date.

4. Elimination of Duplicate Overhead Payment for Outpatient Services (Section 104)

Prior Law: The Secretary is required to establish, by regulation, limitations on costs or charges that are to be considered reasonable for outpatient services provided by hospitals or clinics (other than rural health clinics) and by physicians utilizing those facilities.

Modification: The provision allows the Secretary to issue regulations to limit the reasonable charge for the services of physicians who perform services in hospital outpatient departments to a percentage of the amount of the prevailing charge for similar services furnished in a physician's office, taking into account the extent to which the overhead costs of the department have been included in the hospital's costs or charges.

Effective Date: The provision applies to charges for services rendered on or after October 1, 1982.

5. Prohibiting Payment for Hill-Burton Free Care (Section 106)

Prior Law: In obtaining Federal loan guarantees under the Hill-Burton Act, hospitals and skilled nursing facilities agree to provide a reasonable volume of uncompensated services to persons unable to pay. A recent U.S. Court of Appeals decision held that costs of providing such care were reimbursable under Medicare.

Modification: Requires the Secretary to provide, by regulation, that the costs incurred by a hospital or a skilled nursing facility (SNF) in complying with its free care obligations under the Hill-Burton Act are not reasonable costs for purposes of Medicare reimbursement.

Effective Date: The provision applies to all such costs that have been, or will be incurred, except those recognized by the final judgement of a U.S. Court of Appeals entered into prior to enactment.

6. Prohibiting Payment for Anti-Unionization Activities (Section 107)

Prior Law: The reasonable costs of consultants to hospitals on union organizing activities are recognized by Medicare if these activities do not violate the National Labor Relations Act.

Modification: Medicare reimbursement for costs incurred for activities directly related to influencing employees with respect to unionization would be prohibited.

Effective Date: The provision applies to costs incurred after the date of enactment.

7. Reimbursement of Provider-Based Physicians (Section 108)

Prior Law: Current regulations provide that services furnished by a physician to hospital patients are reimbursed under Part B only if such services are identifiable professional services which contribute to the diagnosis or treatment of individual patients. All other services performed for the hospital (or for a skilled nursing facility) by provider-based specialists (e.g., radiologists, anesthesiologists, pathologists) are reimbursed as provider services on the basis of reasonable costs.

Modification: The provision directs the Secretary to prescribe regulations, which will distinguish between (1) professional medical services which are personally rendered to individual patients; which contribute to the patient's diagnosis and treatment; and are reimbursable under Part B on a charge basis, and (2) professional medical services of practitioners which are of benefit to patients generally and which can be reimbursed only on a reasonable cost basis. Reasonable cost reimbursement for provider based services cannot exceed a reasonable compensation equivalent established by the Secretary in regulations.

Effective Date: For reductions for cost reporting periods ending after September 30, 1982 but only for the portion of the period occurring after that date.

8. Prohibiting Recognition of Payments Under Certain Percentage Arrangements (Section 109)

Prior Law: In determining reasonable costs for home health agencies, the Secretary is to exclude any cost under a contract which determines the amount payable by the home health agency as a percentage of the agency's reimbursement or claim for reimbursement. There are no comparable provisions for other providers.

Modification: Payments made by any provider of services to contractors, employees of related organizations, consultants, or subcontractors would not be reimbursed where compensation is based on percentage arrangements except where such arrangements are reasonable and are part of customary business practice or provide incentives for efficient and economical operations. The provision would also not apply where such costs are subject to limits contained in Section 108 of the bill on reimbursement of provider-based physicians.

Effective Date: The provision is effective upon enactment, except: (1) for percentage arrangements entered into before enactment, the provision applies one year after enactment, or (2) if the provider can unilaterally terminate a percentage arrangement, the provision applies 30 days after the first date that the provider can terminate the arrangement; (3) also, the provision would not apply prior to October 1, 1982 to costs incurred under a percentage arrangement for services of a provider-based physician. Beginning October 1, 1982, the provision would apply only where the limitation on the reimbursement for the services of provider-based physicians (as promulgated in regulations required by Section 108 of this Act) has not been implemented.

9. Eliminating "Lesser of Costs or Charges" Provision (Section 110)

Prior Law: Payment for services furnished by providers is limited to the lower of the provider's actual charge or the reasonable cost of the service.

Modification: The "lower of costs or charges" (LCC) provisions would be eliminated for a class of providers, if and when the Secretary determines and certifies to the Congress that such action will not increase Medicare payments to that class of providers. The Conference Report expresses the intent that such determination would take into account both past experience under the LCC provision and possible changes in cost accounting and charging practices of providers in the absence of the provision. LCC would be reestablished if the Secretary determines that its elimination has increased program costs.

Effective Date: The provision would be effective on the date the Secretary specifies in the certification to Congress.

10. Elimination of Private Room Subsidy (Section 111)

Prior Law: Medicare currently determines its payments to a hospital on the basis of the average costs of all of its accommodations, including the additional costs of private rooms even though Medicare generally does not pay for private rooms that are not medically necessary.

Modification: The provision requires the Secretary to publish regulations eliminating the current Medicare subsidy for medically unnecessary private rooms.

Effective Date: Regulations are to be issued by October 1, 1982, if they are published on an interim basis, final regulations must be issued by January 31, 1983.

11. Radiologist/Pathologist (Section 112)

Prior Law: Under current law, Medicare Part B pays 100 percent of the reasonable charges of radiologists and pathologists who furnish radiology and pathology services to hospital inpatients and who accept assignment in all cases for these services. Such services are not subject to the deductible and coinsurance features of the Part B program.

Modification: The provision eliminates the 100 percent reimbursement rate currently applicable to inpatient radiology and pathology services. Medicare will pay for such services on the same basis as for other physicians' services, i.e., 80 percent of the reasonable charge after the Part B deductible has been met.

Effective Date: The provision is effective for services furnished on or after October 1, 1982.

12. Reimbursement for Assistants at Surgery (Section 113)

Prior Law: Part B carriers have the discretion of reimbursing assistants at surgery, and generally follow local medical practice and/or private sector reimbursement policies.

Modification: The provision prohibits reasonable charge reimbursement for an assistant at surgery in hospitals where an approved training program exists in the specialty and a qualified staff physician is available to provide the service, except when: (1) the surgery is performed by a team of physicians needed to perform complex medical procedures; (2) the patient has multiple conditions which require the presence of, and active care by, a physician of another specialty during surgery; and (3) in the case where exceptional medical circumstances exist. The Secretary may specify other appropriate exceptions by regulations.

Effective Date: The provision is effective with respect to services performed on or after October 1, 1982.

13. Prohibition of Payment for Ineffective Drugs (Section 115)

Prior Law: The Omnibus Budget Reconciliation Act of 1981 (P.L. 97-35, Section 2103) prohibited, effective October 1, 1981, the use of Federal funds under Medicare Part B and under Medicaid to pay for certain drugs. These are prescription drugs that the Food and Drug Administration has determined to be less than effective in use. However, subsequent appropriations legislation barred implementation of Section 2103 of P.L. 97-35 through September 30, 1982 and the Department has provided for continued reimbursement of the drugs.

Modification: The provision authorizes implementation of Section 2103 of P.L. 97-35.

Effective Date: September 30, 1982.

14. Medicare Secondary for Older Workers (Section 116)

Prior Law: The Medicare program is the primary payer except where there is coverage under workers' compensation, automobile medical or no fault insurance and any liability insurance. The Federal Age Discrimination in Employment Act (ADEA), which applies to employers of 20 or more full-time employees, prohibits employment bias on the basis of age for most workers between ages 40 and 70 in the private sector. However, an Interpretive Bulletin now enforced by the Equal Employment Opportunity Commission (EEOC) permits employers to either (1) "carve-out" those benefits that are actually provided by Medicare or (2) supplement Medicare with benefits for services which Medicare was not expected to pay.

Modification: TEFRA changed the manner in which employed individuals age 65 - 69 may be provided health care benefits. Section 116(a) of TEFRA amended the ADEA to require employers of 20 or more employees to offer their age 65 - 69 employees the same health insurance plans as are offered to their younger employees. These benefits must be offered as primary to Medicare. Section 116(b) of TEFRA amended the Social Security Act to make Medicare secondary payer to employer group health plan coverage for employed individuals and their spouses age 65 - 69.

The Conference Report includes language specifying the intent of Congress that an employee will have the option of rejecting the plan offered by the employer, thereby retaining Medicare as primary coverage. The Congress expressed the intention that regulations be issued preventing employers from circumventing this provision by inducing employees over 65 to reject the health benefit plan offered to employees under 65. Thus, employers cannot offer employees secondary coverage for Medicare covered services. They may, however, offer a supplemental plan that covers items and services wholly noncovered by Medicare, such as prescription drugs.

Where the amount paid by an employer group health plan is less than the charge, secondary Medicare benefits may be paid to supplement the amount paid by the employer plan. The general principle is that the provider, physician, or beneficiary should receive no less in combined benefits from the employer plan supplemented by Medicare than would have been received if Medicare had been primary payer and the employer plan secondary. Thus, for participating hospitals and other institutional providers of services, Medicare supplements the employer plan payment up to the Medicare payment rate. Physicians who accept assignment could receive total benefits from the employer plan and Medicare equal to the Medicare reasonable charge. For beneficiaries, Medicare would supplement the primary payment up to the higher of the Medicare reasonable charge or the plan's allowable charge. Amounts paid by an employer group health plan for Medicare covered services are applied to the Medicare deductible and coinsurance amounts.

Effective Date: ADEA was amended effective January 1, 1983. The amendment to the Social Security Act is effective with respect to items and services furnished on or after January 1, 1983.

Modification: This provision requires interest payments with respect to Medicare overpayments and underpayments. The rate of interest would be in conformity with the Treasury Fiscal Requirements Manual. Interest would not begin to accrue until 30 days after the date of the final determination.

Effective Date: The provision is effective for final determinations made on or after the date of enactment.

15. Temporary Delay in Periodic Interim Payments (Section 120)

Prior Law: Hospitals may elect to receive payments for services rendered to beneficiaries on the basis of periodic interim payments based on estimates of covered days. Under this method, lag between provision of service and receipt of payment averages 3 weeks. Providers paid on the basis of submitted bills experience an average lag of up to 6 weeks.

Modification: Delays PIP due during the last 3 weeks of September of both 1983 and 1984, to the following October.

Effective Date: September, 1983 and 1984.

16. Medicare Coverage of Federal Employees (Sections 121 and 278)

Prior Law: Federal employment generally is not covered under Social Security and is therefore not subject to FICA taxes.

Modification: Medicare coverage would be extended to Federal employees, who are required to pay the Hospital Insurance portion of the FICA tax (i.e., 1.3 % of earnings up to a yearly maximum). Federal wages paid after December 31, 1982 are covered for purposes of earning quarters of coverage for determining Medicare eligibility. Persons employed by the Federal government as of January 1983 and at any time prior to that date would, if necessary, have their wages prior to January, 1983 treated as if those wages were covered for purposes of determining Medicare eligibility.

Effective Date: Applies to wages paid in calendar years after 1982.

17. Coverage of Extended Care Services Without Regard to Three Day Prior Hospitalization Requirement (Section 123)

Prior Law: Medicare provides coverage of up to 100 days of "post-hospital extended care services" in a qualified skilled nursing facility (SNF) following a hospital stay by the beneficiary of at least 3 consecutive days.

Modification: This provision would eliminate the 3-day prior hospitalization requirement when the Secretary determines it will not lead to an increase in cost and will not change the acute care nature of the SNF benefit. The Secretary is authorized to impose limits for persons covered without a prior hospital stay on the scope or extent of services covered and on categories of individuals eligible. The 3-day requirement may be reestablished if the Secretary detemines that its elimination has increased program costs.

Effective Date: At such time that the Secretary determines, through reimbursement changes or other adjustments, that elimination of the 3-day requirement will not lead to an increase in cost and will not alter the acute care nature of the benefit.

18. Part B Premium as a Temporary Constant Percentage of Costs (Section 124)

Prior Law: Part B premiums are the lesser of the actuarial rate (that amount required to pay for one-half the expected average cost of the Part B program for the 12 months during which the premium is in effect, with a margin for error) for aged enrollees, or the past year's premium rate increased by the same percentage as the most recent general cost of living adjustment (COLA) to monthly Social Security cash benefits.

Modification: From July 1983 through June 1985, the monthly premium for Part B is set at one-half the actuarial rate (25 percent of the expected average cost with a margin for error) for aged enrollees. After June 1985, calculation of the premium rate would revert to the current law method with the premium amount for July 1984-June 1985 serving as the base from which the July 1986 premium would be calculated. PL 98-21 (enacted 04/83) amended this provision to make it effective 01/84 - 12/85, changed the premium promulgation date to September (from December), and changed the effective date of the new premiums from July to January.

Effective Date: July 1, 1983 through June 30, 1985.

19. Special Enrollment Provisions for Merchant Seamen (Section 125)

Prior Law: Health benefits for merchant seamen under the Public Health Service (PHS) Act were repealed effective September 1981. Seamen who were eligible, but had not previously enrolled in Premium Part A or Part B, had to wait for a General Enrollment Period and pay a late enrollment penalty.

Modification: A special enrollment period was established for merchant seamen beginning with 10/01/82 and ending December 31, 1982. Seamen who documented their former PHS eligibility could enroll in Premium Part A and in Part B without having to pay the late penalty, and could elect retroactive coverage to October 1, 1981 if they enroll before January 1, 1983. The Secretary disseminated information to make seamen aware of this provision.

Effective Date: 10/01/82.

20. Extending Medicare Proficiency Examination Authority (Section 126)

Prior Law: The Secretary of HHS is authorized to conduct a program to determine the proficiency of health care personnel, including clinical laboratory personnel, who do not meet formal educational requirements. The existing authority expired December 31, 1981.

Modification: The authority of the Secretary to determine the proficiency of certain health care personnel would be extended to September 30, 1983.

Effective Date: The provision is effective upon enactment.

21. Prohibiting Retroactivity of Regulations Regarding Access to Books and Records (Section 127)

Prior Law: Section 952 of Public Law 96-499 (the Omnibus Reconciliation Act of 1980) requires the Secretary of HHS or the Comptroller General to have access to the books and records of subcontractors who supply providers with goods and services valued at $10,000 or more over a 12-month period. The law directs the Secretary to prescribe in regulations the procedures and criteria to be used in obtaining access to such books and records. These regulations have not yet been published in proposed form.

Modification: If regulations implementing Section 952 are not issued in final form prior to January 1, 1983, preceded by a comment period of at least 60 days, they may not be applied retroactively.

Effective Date: The provision is effective upon enactment.

22. Audit and Medical Review (Section 118)

Prior Law: Medicare fiscal intermediaries and carriers perform provider cost audits and medical necessity review (to the extent it is not duplicative of PSRO review) of claims using funds appropriated for Medicare contractor budgets. The amount to be spent on audits and medical review is negotiated by each contractor.

Modification: The Medicare contractor budget will be supplemented by an additional $45 million for Fiscal Years 1983, 1984 and 1985 which must be used exclusively for provider audits and medical necessity review.

Effective Date: October 1, 1982.

23. Private Sector Review Initiative (Section 119)

Prior Law: Medicare fiscal intermediaries and carriers perform medical review (to the extent it is not duplicative of PSRO review) of claims and their performance is monitored.

Modification: The Secretary will undertake an initiative to improve medical review performed by Medicare contractors, and will encourage similar efforts by private insurers and other private entities. Specific standards must be developed to measure the performance of Medicare contractors in identifying and reducing unnecessary utilization. Current provisions which waive beneficiaries' liability for payment of services they did not know would be uncovered are confirmed for payment denials made under the review initiative.

Effective Date: Upon enactment.

24. Six-Month Moratorium on Deregulation of Skilled Nursing and Intermediate Care Facilities (Section 135)

Prior Law: The Secretary is authorized to promulgate regulations related to Medicare conditions of participation for SNFs, Medicaid certification and requirements for SNFs and intermediate care facilities (ICFs), and certification procedures for providers.

Modification: This provision imposes a 6-month moratorium on the promulgation of changes in current regulations related to Medicare conditions of participation for SNFs, Medicaid certification and requirements for SNFs and ICFs, and certification procedures for SNFs.

Effective Date: Moratorium continues until the first day of the seventh calendar month beginning after the date of enactment.

25. Utilization and Quality Control Peer Review Program (Sections 141 - 150)

Prior Law: Non-profit Professional Standards Review Organizations (PSROs), composed of licensed physicians in designated local areas, are required to review the medical necessity, quality and appropriateness of health care services provided to Medicare beneficiaries. PSROs receive a Federal grant to perform this review, as well as to analyze profiles of care to identify aberrant patterns. States may contract with PSROs for Medicaid review at a Federal match of 75 percent of the costs. PSROs may not disclose information unless necessary for program purposes, and cannot be held liable on account of any action resulting from the performance of review duties. Physicians and providers failing to meet their obligations under the law may be sanctioned by PSROs.

Modification: The PSRO program is modified by establishing the Utilization and Quality Control Peer Review Organization (UQCPRO) program in its place. The UQCPRO program is very similar to the PSRO program with several important differences. Eligible organizations may be proprietary or non-profit and may be either physician groups or have available sufficient physicians to perform review. Facilities and facility associations are excluded from participating; payor organizations may participate after 12 months. The Secretary will enter into performance contracts with UQCPROs for two years, renewable biennially. Contracts could be terminated only after a panel had reviewed relevant data and information and provided a recommendation to the Secretary. Contract non-renewals would not be subject to termination panel procedures but the UQCPRO would be able to present data and information on its performance. Geographic areas would be consolidated generally into Statewide areas if annual Medicare and Medicaid admissions are fewer than 180,000. No local area could be established with fewer than 60,000 total (both public and private) annual admissions.

UQCPROs will be exempt from the Federal Freedom of Information Act but must disclose relevant information to Federal and State fraud and abuse, licensure and public health agencies. Sanctions will automatically become effective within 120 days if the Secretary fails to act upon a UQCPRO recommendation. The dollar amount triggering hearings and appeals of review decisions has been doubled. Private review is facilitated by requiring participating Medicare hospitals to release data on patients of private payors who contract with UQCPROs. The Secretary cannot terminate or fail to renew any PSRO grants until he enters into a contract with a UQCPRO for the area served by the PSRO. The UQCPRO program has no provision for Statewide or National Councils.

Effective Date: With contracts entered into or renewed on or after enactment (subject to the provision requiring continuance of PSROs pending contracting with UQCPROs).

26. Prospective Payment System for Medicare Inpatient Hospital Services (Sections 601-607 of Public Law 98-21)

Prior Law: The Peer Review Improvement Act of 1982 established the utilization and quality control peer review organization (PRO) program. When fully implemented, this program will replace the existing professional standards review organization (PSRO) program. PROs will assume responsibilities similar to those performed by PSROs for the review of Medicare health care services to assure care is reasonable, medically necessary, and furnished in the appropriate setting, and is of a quality which meets professional standards.

Modification: The Medicare prospective payment system (PPS) modifies the PRO program. Diagnostic related group (DRG) validation under PPS is an important difference. Under PPS, payment for most services provided by hospitals to Medicare beneficiaries is based on a fixed amount, determined in advance for each case, according to one of 468 DRGs into which the case is classified. A DRG is an assignment for a category of patients with similar clinical problems requiring similar amounts of inpatient care and hospital expenditures. The International Classification of Diseases, 9th Revision, Clinical Modification is the coding basis for DRG assignment. This coding system is universally accepted, and provides a single classification of morbidity data for indexing medical records for medical care review. Acute care hospitals under Medicare must enter into contracts with PROs no later than November 15, 1984 to perform the following PRO functions: (1) review of the reasonableness, necessity and appropriateness of hospital admissions; (2) review of the completeness, adequacy, and quality of care provided; (3) validation of diagnoses and procedural information that determine Medicare reimbursement; and (4) review of the necessity and appropriateness of care on an "outlier" basis. The purpose of prospective payment is to change hospital behavior through financial incentives under Medicare to encourage more efficient medical management of health and medical care by doctors and hospitals. Prospective payment incentives require new review strategies to safeguard the Medicare program. These review strategies deal with admissions that trigger payments and with quality of patient care. The focus of the PRO program is to achieve impact, through peer review, on the Medicare system.

27. Hospice Care (Section 122)

Prior Law: Covered services are provided to terminally ill beneficiaries and may be provided in a hospice setting. However, unique hospice services such as outpatient palliative drugs, respite care, bereavement counseling and home health services provided to beneficiaries who are not homebound are not covered and cannot be reimbursed. Hospices are not recognized as distinct providers, although some have been certified under other provider categories.

Modification: Medicare Part A will cover hospice care for beneficiaries having a life expectancy of 6 months or less. Hospice care is available for two periods of 90 days and one period of 30 days in lieu of all other Medicare benefits, except the patient's attending physician and services not related to the terminal condition. Hospices must provide a core of services directly which include nursing care, medical social services, physician services and counseling services. All other services including physical and occupational therapy, speech-language pathology, home health aide/homemaker services, drugs and medical supplies and short-term inpatient care can be provided under arrangements. Inpatient care can comprise no more than 20 percent of aggregate patient days, with inpatient respite care limited to no more than 5 consecutive days on an intermittent basis. A 5 percent coinsurance is imposed on inpatient respite care and a co-payment is placed on drugs at the lesser of $5 or 5 percent per prescription charge.

Care must be available on a 24-hour basis and be provided in accordance with a written plan developed and implemented by an interdisciplinary team composed of one physician, one nurse and one social worker employed by the hospice, as well as one counselor. Hospices are classified as separate providers which must file separate cost reports. Organizations will be deemed to meet any hospice standards identical to standards they currently meet under other provider categories. Reimbursement will be made on the basis of reasonable cost, not to exceed a cap amount equal to 40 percent of the estimated average Medicare expenditures for cancer patients during the last six months of life. No payment may be made for bereavement counseling, and other counseling services may not be rendered as separate services. The Secretary will report to Congress by January 1986 on the equity of the reimbursement method and benefit structure, including the feasibility of prospectively reimbursing hospices. The Secretary will also report, prior to September 30, 1983, on the effectiveness of the hospice demonstration program, which will be continued until implementation of this provision.

Effective Date: November 1, 1983 with a sunset provision of October 1, 1986.

28. Payments to Health Maintenance Organizations and Competitive Medical Plans (Section 114)

Prior Law: Health maintenance organizations (HMOs) are reimbursed by Medicare for services covered under both Parts A and B, pursuant to Section 1876 of the Social Security Act. Section 1876 defines an HMO as a legal entity which generally meets the definition in Title XIII of the Public Health Service Act, and which makes Medicare covered services available in a geographic area on a prepayment basis.

Under Section 1876, HMOs receive interim monthly capitation payments based on either cost or risk contracts. An HMO is eligible to enter into a risk-sharing contract if it has at least 25,000 members and has served as the primary source of health care for at least 8,000 persons in the two years immediately preceding the contract, or serves non-urban areas with current enrollments of not less than 5,000 members and which has served as the primary source of health care for at least 1,500 people in the 3 years immediately preceding the contract.

Under risk contracts, reimbursement is based on a comparison of the HMO's costs with its Adjusted Average Per Capita Cost (AAPCC), which is the average cost of providing services to Medicare beneficiaries in the same geographic area as the HMO but who are not enrolled, and having the same characteristics as the enrolled population. If the risk-based HMO's costs are less than the AAPCC, it shares the "savings" with the Medicare program. The organization may receive savings of up to 10 percent of the AAPCC. HMOs are not required to provide additional services with their savings.

Modification: In addition to cost contracts, the provision authorizes prospective reimbursement under risk sharing contracts with HMOs and other eligible organizations at a rate equal to 95 percent of the AAPCC.

Organizations eligible to enter into contracts are Federally-qualified HMOs or organizations which provide specified health services, receive fixed and periodic payments on behalf of enrollees, provide physician services through staff physicians or physicians under contract, assume financial risk on a prospective basis, and meet financial viability standards. The organization must have at least 5,000 members, although this limitation may be waived for plans in non-urban areas. The organization must provide all Medicare services and the Secretary must approve any additional services. The organization must also have arrangements for an ongoing quality assurance program, in accordance with regulations to be established by the Secretary. An annual open enrollment period of at least 30 days is required. Plans must generally accept beneficiaries in order of application up to capacity. A beneficiary may disenroll on a monthly basis with one month's notice. A plan may not disenroll or refuse to reenroll a beneficiary because of health status or services required. Combined Medicare and Medicaid enrollment in the HMO cannot exceed 50 percent of the total enrollment, except under certain circumstances. The Secretary may establish standards for consumer information to be supplied to eligible beneficiaries.

To the extent that the Medicare payment exceeds the eligible organization's adjusted community rate under a risk-sharing contract, the organization must use the savings to provide its Medicare members with additional benefits (selected by the organization and approved by the Secretary) or reduce cost sharing.

Two new Medicare members will be required to enroll in a plan for each current Medicare enrollee who converts to risk reimbursement.

The Secretary may enter into reasonable cost contracts with eligible organizations which he or she determines do not have the capacity to bear the risk of potential losses under a risk-sharing contract, or which so elect, or which do not meet the membership size limtation.

The Secretary is required to conduct a study on the benefits, in addition to Medicare benefits, which are provided under the new risk reimbursement; and another study on the extent of, and reason for, Medicare beneficiaries terminating membership in HMOs.

Effective Date: The provision will become effective the later of the first day of the thirteenth month after enactment, or one month after the Secretary notifies Congress that the methodology for determining the prospective rate based on 95 percent of the AAPCC is developed and can be implemented.

29. Technical Corrections from Omnibus Budget Reconciliation Acts of 1980 and 1981 (Sections 128 and 137)

Prior Law: The Omnibus Budget Reconciliation Acts of 1980 and 1981 authorized many changes to Title XVIII of the Social Security Act.

Modification: Section 137 makes a number of technical and minor policy changes to the 1981 Reconciliation Act. The policy changes are as follows:

Section 137(b)(26) This provision expands the circumstances under which the Secretary may impose a civil money penalty. Such circumstances now include physician violation of the terms of his assignment under Medicare and provider violation of an agreement with a State agency regarding maximum charges, in addition to the filing of claims for medical services not provided as claimed.

Section 137(c)(1) This provision amends the 1980 Reconciliation Act (P.L. 96-499) to make the coordinated audit requirement applicable to cost reporting periods beginning on or after April 1, 1981 rather than to services provided on or after that date.

In addition, in Section 128 certain corrections were made to technical errors in Title XVIII made in the Omnibus Budget Reconciliation Act of 1981.

Effective Date: These provisions are effective as if they had been originally included in the Reconciliation Act or Social Security Act provisions to which they relate, except as otherwise provided.

PART II

ANNUAL REPORT
ON THE

END-STAGE RENAL DISEASE PROGRAM
(CALENDAR YEAR 1982)

PART II

END STAGE RENAL DISEASE

The End-Stage Renal Disease (ESRD) part of the report is prepared in accordance with Section 1881(g) of the Social Security Act, and addresses the 15 specific requests for data enumerated therein. It covers activities related to the care of ESRD patients that took place in calendar year 1982, and includes information on the number of patients utilizing the various forms of treatment, the costs involved, discussions of cost savings experiments, and basic kidney research conducted during the year.

The total dialysis population increased by 11.6 percent in 1982, to 65,765 from 58,924 in 1981. The home dialysis population increased by 23.9 percent, to 11,733 from 9,474 in 1981. The net increase in home patients was due largely to the growth of continuous ambulatory peritoneal dialysis (CAPD) from 4,347 patients in 1981 to 6,523 patients in 1982. CAPD now accounts for 55.6 percent of all home patients. At the end of 1982, the home dialysis population accounted for 17.8 percent of the total dialysis population, a net increase of 1.7 percent over 1981.

The number of transplants performed increased by 9.7 percent in 1982, to 5,358 from 4,885 in 1981. Patients transplanted in 1982 accounted for 7.0 percent of the total ESRD population, a net decrease of 0.7 percent over 1981. The percentage of total transplants performed with kidneys from living related donors increased 15.0 percent over 1981 figures, while cadaveric transplants increased 7.4 percent.

Total expenditures for services rendered during calendar year 1982 were more than $1.6 billion, based on bills posted as of December 31, 1983. The 1982 figure will increase as bills continue to be posted. The average payment rate for both hospital and freestanding dialysis units for dialysis was $156 per treatment without physicians' fees. The average kidney acquisition charge in 1982 was $9,009 for a living related donor kidney and $8,818 for a cadaveric kidney. The average estimated kidney acquisition costs were $7,769 and $7,636, respectively. The average estimated cost for a transplant in 1982 was $26,036, excluding physicians' services.

TABLE OF CONTENTS

Chapter I - GENERAL

PAGE

A Legislative Background....124
B. Scope of Report....125
C. ESRD Highlights....126
D. ESRD Program Growth....128
E. Data Collection....129

Chapter II - FACILITIES

A. ESRD Facilities Surveyed and Reporting by State in 1982....132
B. Number of Certified ESRD Facilities since 1973....134
C. Dialysis Facilities, Hospital - 1982....135
D. Dialysis Facilities, Independent - 1982....136
E. Type of Ownership - Profit vs. Non-profit - 1982....137
F. Minimum Utilization Rate Status of Facilities....138
G. Minimum Utilization Rate Status Dialysis - 1982....140

Chapter III - DIALYSIS

A. Dialysis Patient Profile (Total, Incenter, Home, Self-Care)....142
B. New Patient Characteristics (Total, Incenter, Home, New Starts)....149
C. Continuous Ambulatory Peritoneal Dialysis (CAPD) National Patient Registry....151

Chapter IV - TRANSPLANT

A. Summary of Transplant Activity....154
B. Transplants Performed During 1982 - By State....155
C. Transplant Types By Network - 1982....156
D. Transplants 1981 - 1982....157
E. Patients Awaiting Transplants vs Transplants Performed....158
F. Transplant Failures....159
G. ESRD Network Distribution of Transplants Arrayed by Number of Transplants Performed....160

Chapter V - COST

A. Hospitalization for Ancillary Problems....162
B. Kidney Acquisition Costs and Charges....165
C. Independent Organ Procurement Agencies....169
D. Dialysis Payment Rates....170
E. Changes In Dialysis Rates....170
F. Transplant Procedures....174
G. Physician Services....174
H. Projected Enrollment and Benefit Payments for the ESRD Program....176

PAGE

Chapter VI - ESRD STATISTICS

A. Medicare Eligibility Status of Patients being Treated by Medicare Certified ESRD Facilities....178

B. Variation in Medicare ESRD Program Incidence by State....179

C. Mortality and Survival Rates....182

D. Mortality and Graft Failure Rates....188

E. Inpatient Utilization....196

F. Ratio of Patients Trained for Home Dialysis and Dialysis Patients Transplanted to Average Number of Dialysis Patients, 1979-1982....202

G. Major Reasons for Changes in the Number of Patients Treated by Medicare Certified Suppliers of ESRD Services, 1979-1982....203

Chapter VII - MISCELLANEOUS

A. Cost-Savings and Other ESRD Experiments....206

B. Results of Basic Kidney Disease Research....224

C. ESRD Network Organizations....239

D. Appendix - Tables and Figures....241

CHAPTER I

GENERAL

CHAPTER I. GENERAL

A. LEGISLATIVE BACKGROUND

The End-Stage Renal Disease (ESRD) program of Medicare was established by Section 299I of the Social Security Amendments of 1972 (P. L. 92-603). That law extended Medicare coverage to individuals who have permanent kidney failure, require either dialysis or transplantation, and meet certain other eligibility requirements. In general, in order to be eligible for ESRD program benefits, a person must be undergoing a regular course of renal dialysis or have had a kidney transplant, and must be either: (1) fully or currently insured under social security at the onset of the disease; (2) a monthly social security beneficiary; or (3) the spouse or dependent child of an eligible person.

The Health Care Financing Administration (HCFA) is assigned the primary responsibility for overseeing the medical, fiscal, and related aspects of the ESRD program. In addition to using carriers and intermediaries, which contract with the Federal Government to reimburse providers and others for services rendered, End-Stage Renal Disease Networks were intended to aid in the administration of the ESRD program by promoting high quality care in ESRD dialysis and transplant facilities, and the efficient distribution and utilization of resources in the delivery of renal services. An ESRD Network is an approved organized group of ESRD facilities in a designated geographic area which collectively furnishes the necessary care for ESRD patients in the population served. Thirty-two Networks are operational in each of the 50 States and U.S. territories (see Appendix D). As specified in legislation and regulation, Networks are expected to accomplish several functions, which include increasing the use of home dialysis and renal transplantation, monitoring facility patient care planning, establishing standards for patient care, encouraging rehabilitation, and analyzing and exchanging medical care data.

Over the last few years, the End-Stage Renal Disease program has experienced significant increases in the patient base and program expenditures. During 1981, it was determined that emphasis should be placed on efforts to effectively contain costs and influence the selection of economical modalities of care while maintaining quality of care.

On August 13, 1981, Congress passed the Omnibus Reconciliation Act of 1981 (P.L. 97-35). Section 2145 of that Act amended Section 1881 of the Social Security Act, requiring HCFA to develop a prospective reimbursement system for outpatient maintenance dialysis that promotes home dialysis. The Act instructed the Department of Health and Human Services to reimburse home dialysis and infacility dialysis under composite rates or use some other method that, after detailed analysis, is determined to be more efficient and to promote home dialysis more effectively. Section 2145 also revised the provisions regarding reimbursement for physicians' services to provide incentives for the increased use of home dialysis.

As a result, HCFA devoted its resources during 1981 to formulating proposed regulations which would implement the mandate of Section 2145 of the Omnibus Reconciliation Act of 1981.

B. SCOPE OF REPORT

This report will address the items specified in Section 1881(g) of the Social Security Act, which requires the following information:

1. The number of patients, nationally and by renal disease Network, on dialysis (self-dialysis or otherwise) at home and in facilities.
2. The number of new patients entering dialysis at home and in facilities during the year.
3. The number of facilities providing dialysis and the utilization rates of those facilities.
4. The number of kidney transplants, by source of donor organ.
5. The number of patients awaiting organs for transplant.
6. The number of transplant failures.
7. The range of costs of kidney acquisitions, by type of facility and by region.
8. The number of facilities providing transplants and the number of transplants performed per facility.
9. Patient mortality and morbidity rates.
10. The average annual cost of hospitalization for ancillary problems in dialysis and transplant patients, and drug costs for transplant patients.
11. Medicare payment rates for dialysis, transplant procedures, and physician services, along with any changes in such rates during the year and the reasons for those changes.
12. The results of cost-saving experiments.
13. The results of basic kidney disease research conducted by the Federal Government, private institutions, and foreign governments.
14. Information on the activities of Medical Review Boards and other Network organizations.
15. Estimated program costs over the next five years.

C. END-STAGE RENAL DISEASE PROGRAM HIGHLIGHTS December 31, 1982

REIMBURSEMENT[1]

The following table shows reimbursement made by the Medicare program for services provided to ESRD patients in 1982:

Type of Payment	Amount of Payment (Millions)*
Inpatient	$ 505.2
Outpatient	777.3
Physician/Supplier	348.5
Home Health/Skilled Nursing Facility	6.4
Total	$1637.4

*Not Final Figures

DIALYSIS TREATMENT MODALITIES[2]

Dialysis Type and Setting		Number of Patients as of: 12/31/81	12/31/82
In-Unit Staff-assisted Hemodialysis		46,848	51,499
In-Unit Staff-assisted Peritoneal Dialysis		932	874
In-Unit Self-hemodialysis		1,030	1,060
In-Unit Self-peritoneal Dialysis		7	11
Home Hemodialysis		4,480	4,394
Home Peritoneal Dialysis		645	816
Continuous Ambulatory Peritoneal Dialysis		4,333	6,523
Self-dialysis Training:	Hemodialysis	352	408
	Peritoneal	26	19
	CAPD	117	161
Total Dialysis Patients		58,770	65,765

RENAL TRANSPLANTS[2]

The following table shows the number of transplants performed for calendar years 1981 and 1982, by type of donor:

Type of Donor	1981	1982
Living	1,458	1,677
Cadaveric	3,425	3,681
Total	4,883	5,358

TRANSPLANT CHARGES[3]

Average kidney acquisition charges for 1982 were:

Living related donor kidney	$9,009
Cadaveric donor kidney	$8,818

RENAL FACILITIES[4]

These figures represent the facilities approved to provide maintenance dialysis services to ESRD patients as of December 21, 1982:

Total	Profit			Non-Profit		
	Hospitals	Free-Standing Facilities	Hospital Satellites	Hospitals	Free-Standing Facilities	Hospital Satellites
1218	14	423	0	643	104	34

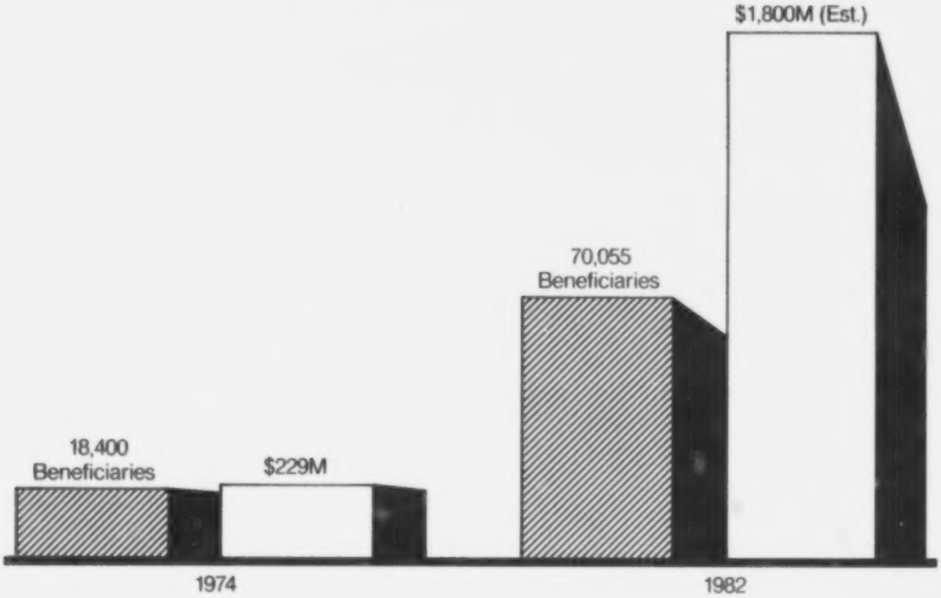
---

1. Source: Weekly Health Insurance Merge (WHIM) Record (HCFA).
2. Source: ESRD Facility Survey Tables (BSS, HCFA).
3. Source: Bureau of Eligibility, Reimbursement and Coverage (HCFA).
4. Source: National Listing of Providers Furnishing Kidney Dialysis and Transplant Services (BSS, HCFA)

D. ESRD Program Growth

Figure 1

ESRD Program Growth



E. DATA COLLECTION

All information concerning the numbers of patients in the various treatment modalities, and the number of transplants performed, was gathered through use of a data collection form known as the End-Stage Renal Disease Facility Survey. For 1982, the Facility Survey was distributed twice, the first time to cover the first six months of calendar year 1982, and the second time to cover the last six months of the year.

A total of 1190 facilities which perform some form of maintenance dialysis and 156 hospitals which perform kidney transplants were requested to complete a Facility Survey (see Table 1). The rate of compliance with that request was 100 percent.

The number of facilities surveyed does not equal the total number of ESRD certified facilities in the country. Some ESRD hospitals were excluded from consideration because they provide only backup dialysis on an acute basis, rather than routine outpatient maintenance dialysis. Other facilities were not requested to complete a Facility Survey because they were so recently certified there was not sufficient time to include them in the survey population.

The data reported via the Facility Survey delineates totals for all patients with end-stage renal disease. That is, the data are not differentiated between patients who have attained entitlement to Medicare benefits and those who have not, within the various treatment modalities.

Although we have no data to definitely indicate what portion of the patients in any particular treatment modality were recipients of Medicare benefits, we know through the Facility Survey that at the end of 1982, 87.8 percent of all patients were entitled to Medicare benefits, 6.1 percent had applications for Medicare entitlement pending, and 6.1 percent were not Medicare eligible.

CHAPTER II

FACILITIES

TABLE 1.

A. ESRD FACILITIES SURVEYED AND REPORTING BY STATE

STATE	DIALYSIS FACILITY SURVEYED AND REPORTING	TRANSPLANT FACILITY SURVEYED AND REPORTING
Alabama	21	1
Alaska	1	0
Arizona	19	4
Arkansas	16	2
California	137	13
Colorado	12	1
Connecticut	15	2
Delaware	3	0
Washington, D.C.	11	5
Florida	71	4
Georgia	35	4
Hawaii	7	1
Idaho	2	0
Illinois	66	7
Indiana	14	2
Iowa	10	1
Kansas	5	2
Kentucky	15	2
Louisiana	37	5
Maine	4	1
Maryland	24	3
Massachusetts	23	7
Michigan	37	10
Minnesota	14	3
Mississippi	18	1
Missouri	25	6
Montana	4	0
Nebraska	8	1
Nevada	3	0
New Hampshire	4	0
New Jersey	26	3

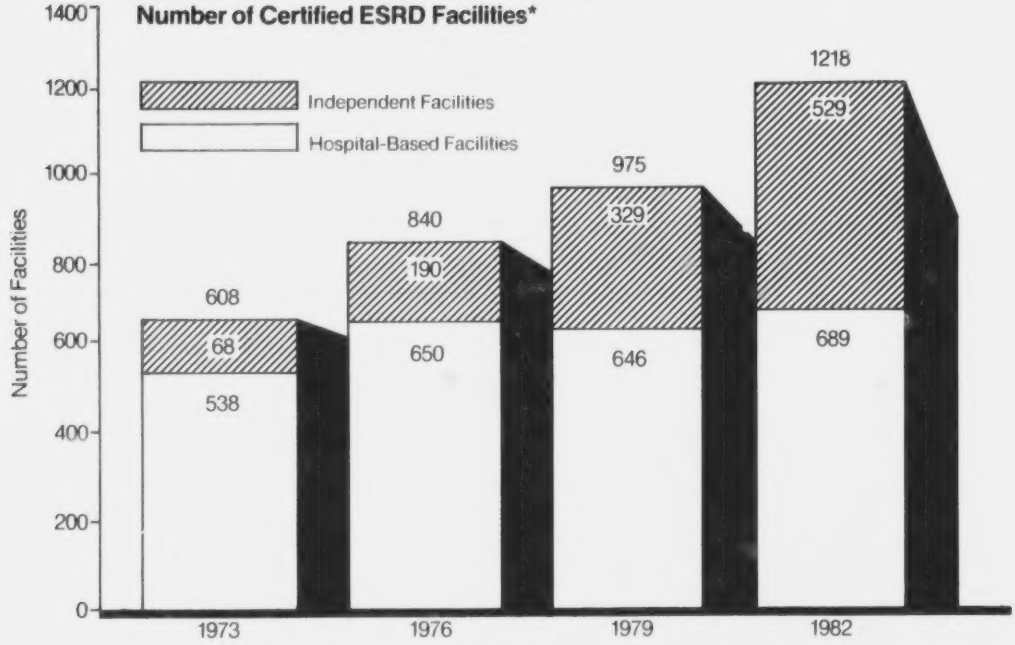
New Mexico	12	1
New York	88	13
North Carolina	20	5
North Dakota	4	0
Ohio	38	9
Oklahoma	17	4
Oregon	7	1
Pennsylvania	74	8
Puerto Rico	13	1
Rhode Island	5	0
South Carolina	17	1
South Dakota	6	0
Tennessee	25	2
Texas	74	8
Utah	14	1
Vermont	1	1
Virgin Islands	2	0
Virginia	39	4
Washington	13	4
West Virginia	9	0
Wisconsin	22	2
Wyoming	1	0
American Samoa	1	0
Guam	1	0
TOTALS	1,190	156

Source: ESRD MEDICAL INFORMATION SYSTEM 1982 FACILITY SURVEYS

B. Number of Certified ESRD Facilities Since 1973

Figure 2

Number of Certified ESRD Facilities*



SOURCE: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1983—HCFA

*This includes all ESRD Medicare approved facilities, not just those providing outpatient maintenance dialysis.

C. Dialysis Facilities, Hospital - 1982

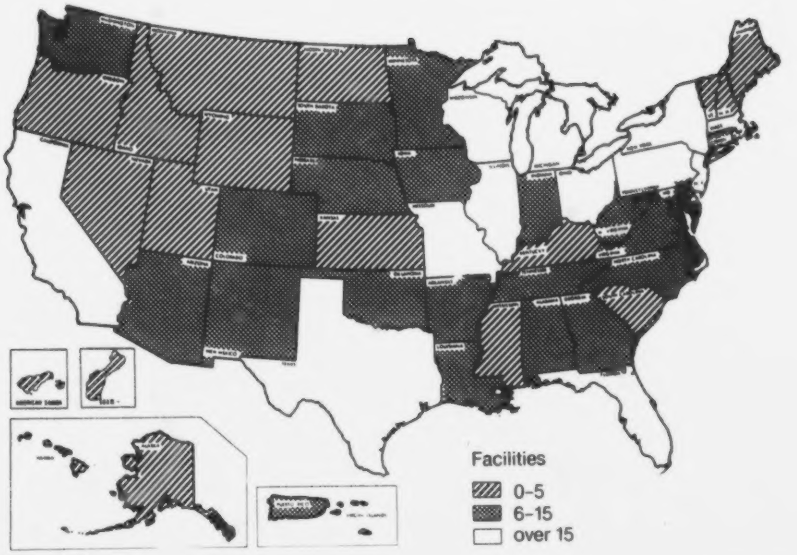

Facilities
▨ 0-5
▩ 6-15
☐ over 15

Figure 3

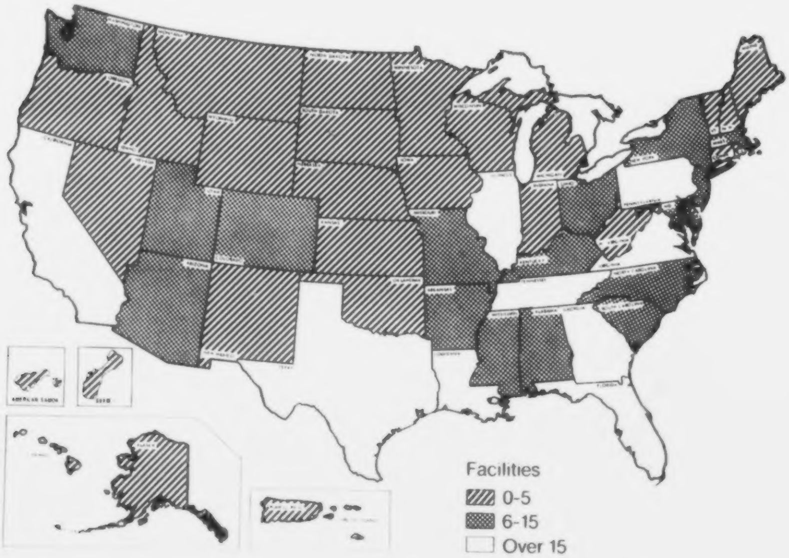
Dialysis Facilities, Hospital—1982

SOURCE: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1983—HCFA

D. Dialysis Facilities, Independent - 1982

Figure 4.

Dialysis Facilities, Independent—1982

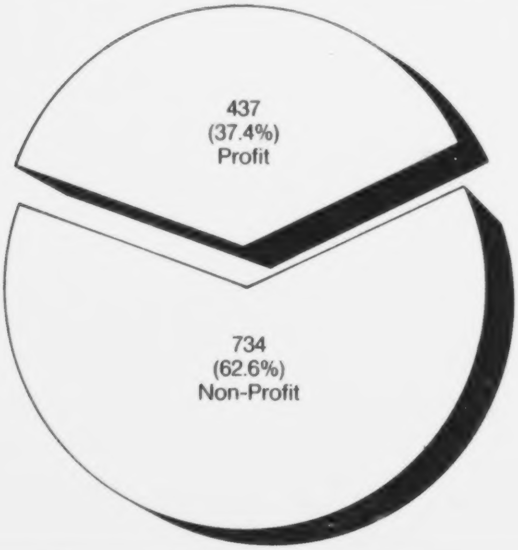

Facilities
▨ 0-5
▩ 6-15
☐ Over 15

Source: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1983—HCFA

E. Type of Ownership - Profit vs. Non-Profit-1982

Figure 5

Type of Ownership—Profit vs. Non-Profit, 1171 ESRD Dialysis Providers, 1982



SOURCE: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1983—HCFA

F. Minimum Utilization Rate Status of Facilities

As of December 1982, there were 1,218 hospitals and facilities approved to furnish dialysis and transplantation services. Of these, 689 were hospital based and 529 non-hospital based. Of the hospital based facilities, 8 provided transplantation services only, 149 provided both dialysis and transplantation, and 532 provided only dialysis services.

The number of certified facilities increased in 1982 by approximately 5 percent (56). Of these, 13 were hospital based and 43 non-hospital based. The number of approved dialysis stations has increased by approximately 4.8 percent (654).

Each approved dialysis facility is certified to provide any of a variety of specialized services. These services include staff-assisted dialysis, home or self-dialysis training, and CAPD training. Over 60 percent (750) of the approved facilities are certified to provide some type of home self-dialysis training and approximately 18 percent are approved to provide in-center self-care dialysis.

As a condition of coverage, all approved ESRD facilities are required to meet minimum utilization rates (MURs). Regulations specify the MURs for which a facility will receive either an unconditional or conditional certification. However, regulations permit an exception to the MUR requirements for a facility that is determined not to have sufficient patients in its service area to meet such a rate, if the facility's absence would adversely affect the achievement of ESRD program objectives.

A total of 1,197 certified facilities have been classified by MUR. The remaining 21 facilities are either facilities which provide back-up dialysis only, and thus do not have an MUR status, or have not been reported.

Figure 6 shows the number of dialysis facilities which have been classified according to the MUR criteria established in regulations.

As of December 1982, there were 157 hospitals approved by the ESRD program as transplant centers.

Transplant centers are grouped according to the minimum utilization rate (MUR) certification standards in Table 2 below. To achieve unconditional certification, a hospital must perform 15 or more transplants per year; for conditional certification, a hospital must perform 7-14 transplants per year; for exception certification, a hospital must perform less than seven transplants per year. One view is that transplantation success is more predictable at centers performing large numbers of procedures. Exception certification is granted only when requiring a higher level of performance would adversely affect ESRD program objectives, such as when a pediatric transplant center has low utilization.

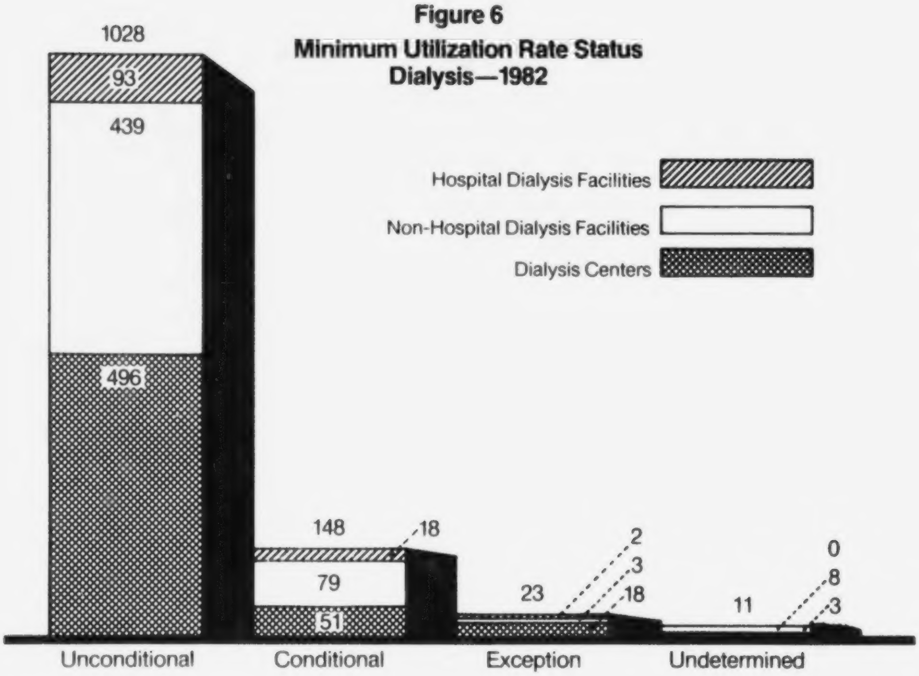
TABLE 2.

MINIMUM UTILIZATION RATE STATUS - TRANSPLANT

	Total	Unconditional	Conditional	Exception	Undetermined
Transplant Center	157	117	29	1 10	

G. Minimum Utilization Rate Status Dialysis - 1982

Figure 6
Minimum Utilization Rate Status Dialysis—1982



SOURCE: The National Listing of Providers Furnishing Kidney Dialysis and Transplant Services. January 1983—HCFA

CHAPTER III

DIALYSIS

A. DIALYSIS PATIENT PROFILE

See Table 10 and Figures 7, 8, 9, 10 and 11

TOTAL

The total number of ESRD patients receiving dialysis continues to grow. As of December 31, 1982, the total dialysis population was 65,765.

INCENTER

The number of patients receiving their treatment in facilities was 54,032. This represents 82.2 percent of the total dialysis population. Of the incenter population, 52,373, or 96.9 percent, were receiving staff-assisted outpatient maintenance dialysis; 1,071, or 2.0 percent, were performing incenter self-dialysis; and 588, or 1.1 percent, were undergoing self-care dialysis training.

HOME

The proportion of patients being treated at home is slowly increasing. There were 11,733 patients dialyzing at home at the end of 1982. This represents 17.8 percent of the total dialysis population. Of the home dialysis population, 4,394, or 37.5 percent, were using hemodialysis; 816, or 6.9 percent, were using peritoneal dialysis; and 6,523, or 55.6 percent, were using continuous ambulatory peritoneal dialysis (CAPD).

SELF CARE

Overall, patients performing some form of self-care comprise 20.4 percent of the total dialysis population. The distribution of patients in self-care over the last four years is as follows:

TABLE 3.
ANNUAL DISTRIBUTION OF SELF-CARE DIALYSIS PATIENTS

Treatment Setting	1979	1980	1981	1982
Home	5,968	7,661	9,474	11,733
Incenter	620	781	1,038	1,071
Training	519	521	495	588
Total:	7,107	8,963	11,007	13,392
Percent of Total Dialysis Population	15.7%	17.1%	18.7%	20.4%

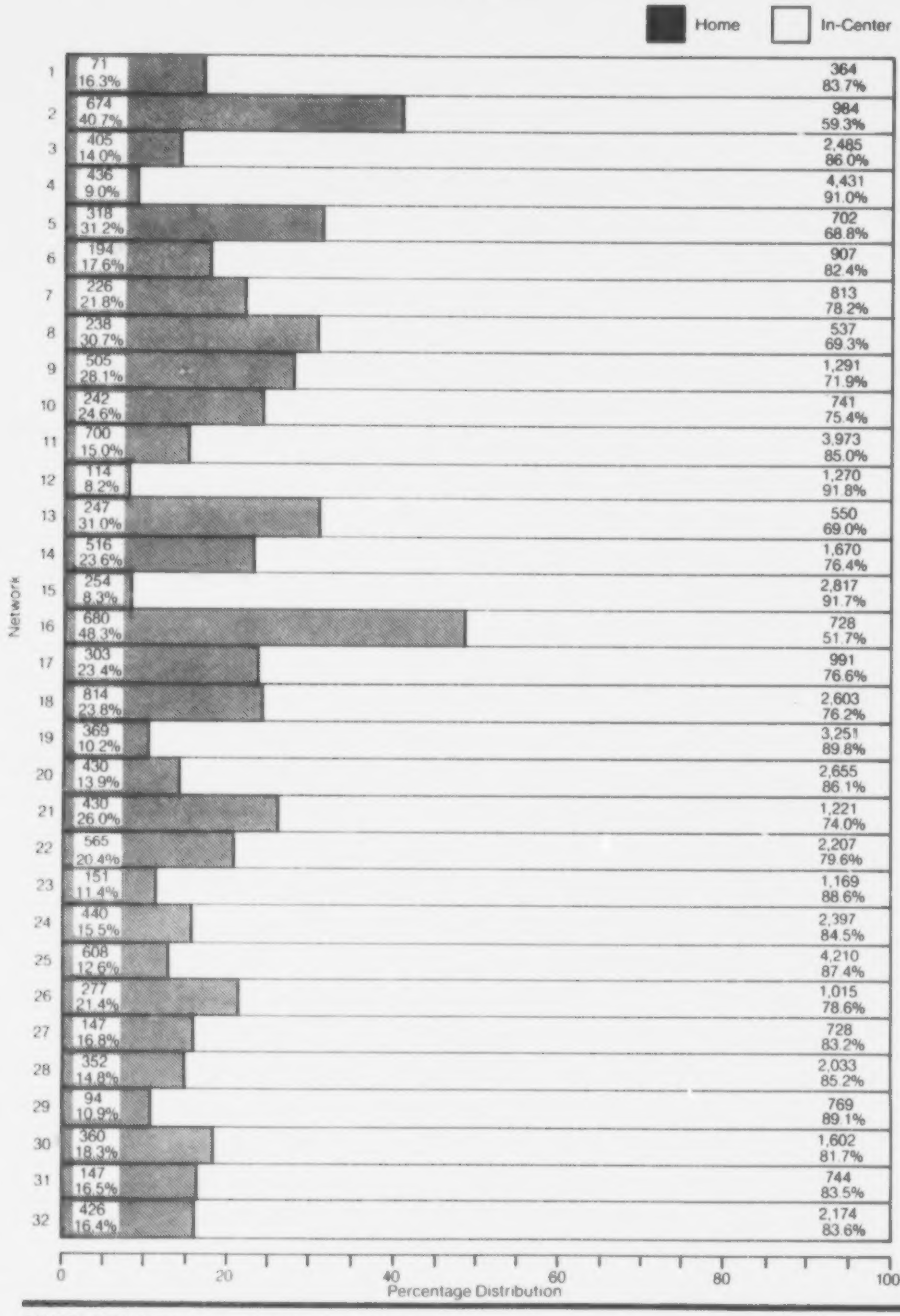
TABLE 4. PATIENTS RECEIVING CARE AS OF 12/31/82

ESRD Network	Facilities Surveyed & Reporting	Total Patients	Staff Assisted Dialysis		Self-Dialysis In-Unit		Self-Dialysis Training			Home Patients		
			Hemo	Peri	Hemo	Peri	Hemo	Peri	Capd	Hemo	Peri	Capd
1	9	435	230	1	120	0	10	1	2	36	11	24
2	27	1,658	925	21	4	0	22	1	11	466	42	166
3	52	2,890	2,357	4	94	0	24	0	6	139	10	236
4	88	4,867	4,306	7	73	0	34	0	9	90	26	320
5	28	1,020	668	5	24	0	2	0	3	199	19	100
6	31	1,101	892	2	8	0	1	0	4	47	3	144
7	27	1,039	804	4	0	0	1	1	3	123	17	86
8	18	775	522	5	0	0	7	1	2	79	27	132
9	31	1,796	1,263	3	0	0	13	0	10	199	16	290
10	32	983	709	25	0	0	3	0	4	81	17	144
11	74	4,673	3,787	21	112	0	37	3	13	199	92	409
12	37	1,384	1,249	18	2	0	1	0	0	27	23	64
13	22	797	489	16	38	0	1	0	6	60	3	184
14	34	2,186	1,535	98	17	0	13	1	4	142	28	346
15	63	3,071	2,607	80	109	0	13	0	8	79	11	164
16	14	1,408	701	4	2	0	17	0	4	286	0	394
17	23	1,294	918	29	33	0	4	0	7	57	0	246
18	65	3,417	2,572	5	7	0	14	1	4	339	89	386
19	71	3,620	3,221	16	6	0	5	0	3	80	25	264
20	53	3,085	2,549	28	65	0	12	0	1	144	31	255
21	20	1,651	1,211	2	0	0	6	1	1	179	63	188
22	47	2,772	2,054	107	21	0	18	1	6	115	39	411
23	23	1,320	1,143	9	13	0	2	0	0	37	0	114
24	59	2,837	2,288	12	57	8	23	4	5	126	57	257
25	65	4,818	4,024	123	30	1	21	0	11	326	7	275
26	24	1,292	898	20	67	0	26	0	4	121	20	136
27	15	875	682	14	16	1	1	0	14	27	3	117
28	37	2,385	1,996	18	9	0	4	1	5	181	28	143
29	15	863	732	37	0	0	0	0	0	57	8	29
30	43	1,962	1,560	23	0	0	16	1	2	129	44	187
31	17	891	652	30	48	1	8	2	3	59	24	64
32	26	2,600	1,955	87	81	0	45	0	6	165	33	228
Total	1,190	65,765	51,499	874	1,060	11	408	19	161	4,394	816	6,523

Source: ESRD Medical Information System 1982 Facility Surveys

Number of Patients in Each Dialysis Treatment Setting by Network - 1982

Figure 7
Number of Patients in Each Dialysis Treatment Setting By Network—1982

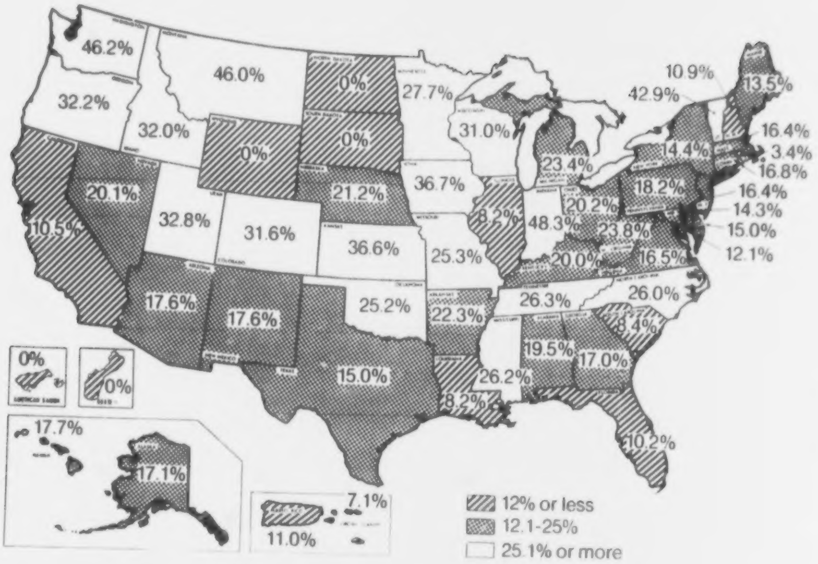


SOURCE ESRD Medical Information System 1982 Facility Surveys

Home Dialysis Patients - 1982

Figure 8

Home Dialysis Patients—1982

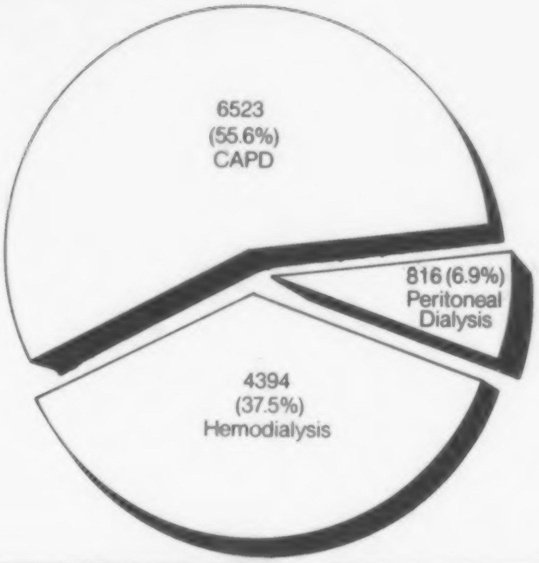

46.2%
32.2%
46.0%
32.0%
0%
0%
0%
27.7%
31.0%
36.7%
21.2%
20.1%
10.5%
32.8%
31.6%
36.6%
25.3%
8.2%
48.3%
23.4%
20.2%
23.8%
20.0%
16.5%
18.2%
14.4%
10.9%
42.9%
13.5%
16.4%
3.4%
16.8%
16.4%
14.3%
15.0%
12.1%
26.3%
26.0%
8.4%
17.6%
17.6%
25.2%
22.3%
19.5%
17.0%
26.2%
8.2%
15.0%
10.2%
0%
0%
17.7%
17.1%
7.1%
11.0%
▨ 12% or less
▩ 12.1-25%
☐ 25.1% or more

Source: ESRD Medical Information System 1982 Facility Surveys

Home Dialysis Modality - 1982

Figure 9

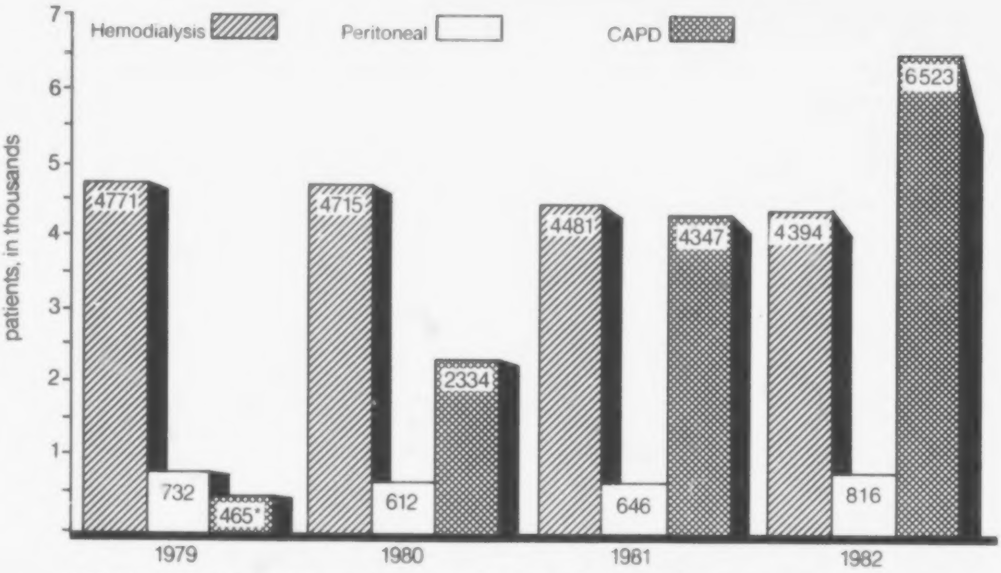
Home Dialysis Modality—1982



SOURCE: ESRD Medical Information System 1982 Facility Surveys

Home Patient Modalities (Hemodialysis, Peritoneal and CAPD)

Figure 10
Home Patient Modalities (Hemodialysis, Peritoneal and CAPD)

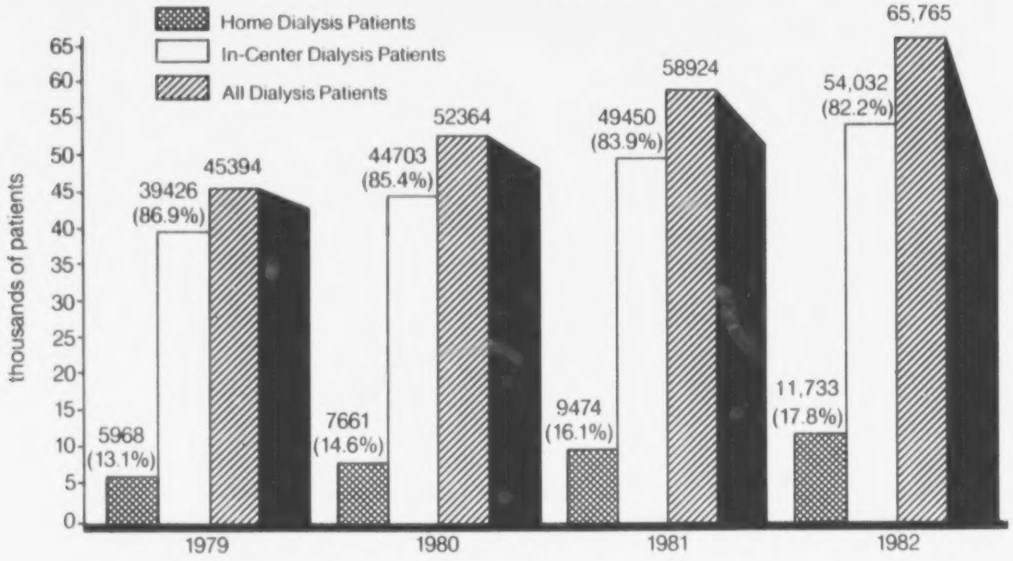


SOURCE: ESRD Medical Information System 1979, 1980, 1981 and 1982 Facility Surveys
*Payment began for CAPD in 9/79. Reportings for CAPD probably misrepresented as "Peritoneal."

Number of Chronic Dialysis Patients Being Treated by Medicare Certified Suppliers of ESRD Services in the United States by Treatment Setting January 1979 - December 1982

Figure 11

Number of Chronic Dialysis Patients Being Treated by Medicare Certified Suppliers of ESRD Services in the United States by Treatment Setting January 1979–December 1982



SOURCE: ESRD Medical Information System 1979, 1980, 1981 and 1982 Facility Surveys

B. NEW PATIENT CHARACTERISTICS

See Table 5 and Figure 12

TOTAL

The total dialysis population increased by 6,841 patients from 58,924 in 1981 to 65,765 in 1982. This is an increase of 11.6 percent.

INCENTER

The incenter dialysis population increased by 4,582, which is an increase of 9.3 percent. However, the proportion of the total dialysis population represented by incenter dialysis patients decreased from 83.9 percent in 1981 to 82.2 percent in 1982.

HOME

The home dialysis population increased by 2,259, which is an increase of 23.8 percent. The portion of the total dialysis population represented by home dialysis patients increased from 16.1 percent in 1981 to 17.8 percent in 1982.

NEW STARTS

Of the 22,797 patients starting a course of dialysis for the first time ever during 1982, 2,699, or 11.8 percent, chose home dialysis and 20,098, or 88.2 percent, chose incenter dialysis. Comparable figures for 1981 were 1,948, or 9.1 percent, of the new starts choosing home dialysis and 19,419, or 90.9 percent, choosing incenter dialysis.

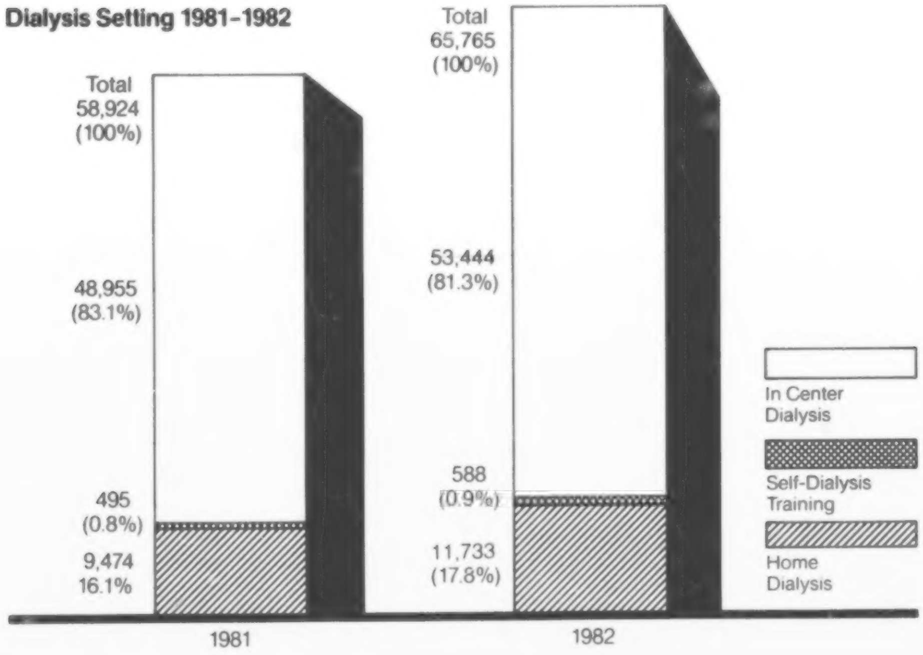
TABLE 5.

NUMBER AND PERCENT INCREASE OF DIALYSIS PATIENTS

	1981	1982	Increase	Percent Increase
Total Dialysis Population	58,924	65,765	6,841	11.6%
Incenter Dialysis Population	49,450	54,032	4,582	9.3%
Home Dialysis Population	9,474	11,733	2,259	23.8%

Dialysis Setting 1981 - 1982

Figure 12



SOURCE: ESRD Medical Information System 1981 and 1982 Facility Surveys

C. CONTINUOUS AMBULATORY PERITONEAL DIALYSIS NATIONAL PATIENT REGISTRY

One of the research objectives of the Chronic Renal Disease Program of the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases is to improve maintenance therapies for end-stage renal disease patients. As part of the Program's effort to evaluate and improve therapies, the Institute has sponsored the development and initial operation of a registry for patients being maintained on Continuous Ambulatory Peritoneal Dialysis (CAPD). Objectives of the registry are to obtain data on peritonitis episodes, catheter/exit tunnel injections (with bacteriologic characterization), catheter replacements, patient training, frequency of hospitalizations, type of renal diseases, time on dialysis, transfer to other therapies, mortality, morbidity, rehabilitation, and on limited demographic information. Data from the registry will be made available to investigators and clinicians for the evaluation of CAPD.

In 1980 the CAPD Advisory Committee to NIH recommended that the Chronic Renal Disease Program initiate a registry of patients being maintained on CAPD. One of the primary reasons for this recommendation was the lack of availability of data on such patients from other sources. The committee recommended operation of a CAPD registry over a limited time period as an interim measure for generation of data to assist in the evaluation of this maintenance therapy.

The development of methodology for the CAPD Patient Registry, its pilot testing with the voluntary cooperation of nine dialysis centers for a six-month period, as well as the initial operation of a national basis has been conducted through a contract with the University of Missouri which houses the Clinical Coordinating Center. The project includes a subcontract with the University of Texas, Austin, for operation of the Data Coordination Center. Two forms are in use for data acquisition: A Patient Registration Form and a Patient Status Form. Currently, the Patient Status Form is submitted quarterly by the cooperating centers to the Data Coordinating Center. Implementation of the Registry on a nationwide basis began July 1, 1981. As of October 20th, 1982, there were 254 participating centers (a total of 5117 patients were registered since the inception of the Registry).

CHAPTER IV

TRANSPLANT

A. SUMMARY OF TRANSPLANT ACTIVITY

See Table 6 and Figures 13, 14, and 15

During 1982, 5,358 kidney transplants were performed. This represents an increase of 473 transplants, or 9.7 percent, over the 4,885 transplants performed in 1981. The number of living related donor transplants in 1982 was 1,677, an increase of 219 (15.0 percent) such transplants over the 1981 figure of 1,458. Cadaveric transplants, on the other hand, increased by 254 (7.4 percent) to 3,681 from 3,427 such transplants in 1981.

B. TRANSPLANTS PERFORMED DURING 1982 - BY STATE

Table 6.

STATE	FACILITIES SURVEYED & REPORTING	TOTAL PATIENTS	TOTAL TRANSPLANTS	LIVING DONOR	CADAVERIC DONOR
Alabama	1	132	132	54	78
Arizona	4	62	62	30	32
Arkansas	2	17	17	15	2
California	13	602	603	178	425
Colorado	1	44	44	11	33
Connecticut	2	56	56	20	36
Washington, D.C.	5	121	121	25	96
Florida	4	197	197	75	122
Georgia	4	75	75	31	44
Hawaii	1	12	12	1	11
Illinois	7	210	210	58	152
Indiana	2	73	73	31	42
Iowa	1	59	60	7	53
Kansas	2	58	58	14	44
Kentucky	2	79	79	19	60
Louisiana	5	78	78	22	56
Maine	1	22	22	3	19
Maryland	3	75	75	21	54
Massachusetts	7	221	221	81	140
Michigan	10	267	267	69	198
Minnesota	3	266	266	122	144
Mississippi	1	30	30	1	29
Missouri	6	139	139	50	89
Nebraska	1	34	34	1	33
New Jersey	3	82	82	13	69
New Mexico	1	27	27	12	15
New York	13	426	429	108	321
North Carolina	5	138	142	37	105
Ohio	9	294	298	111	187
Oklahoma	4	44	44	17	27
Oregon	1	76	76	22	54
Pennsylvania	8	317	318	68	250
Puerto Rico	1	14	14	13	1
South Carolina	1	40	40	17	23
Tennessee	2	168	168	71	97
Texas	8	372	372	110	262
Utah	1	20	20	11	9
Vermont	1	14	14	3	11
Virginia	4	79	79	18	61
Washington	4	92	93	37	56
Wisconsin	2	211	211	70	141
TOTAL	156	5,343	5,358	1,677	3,681

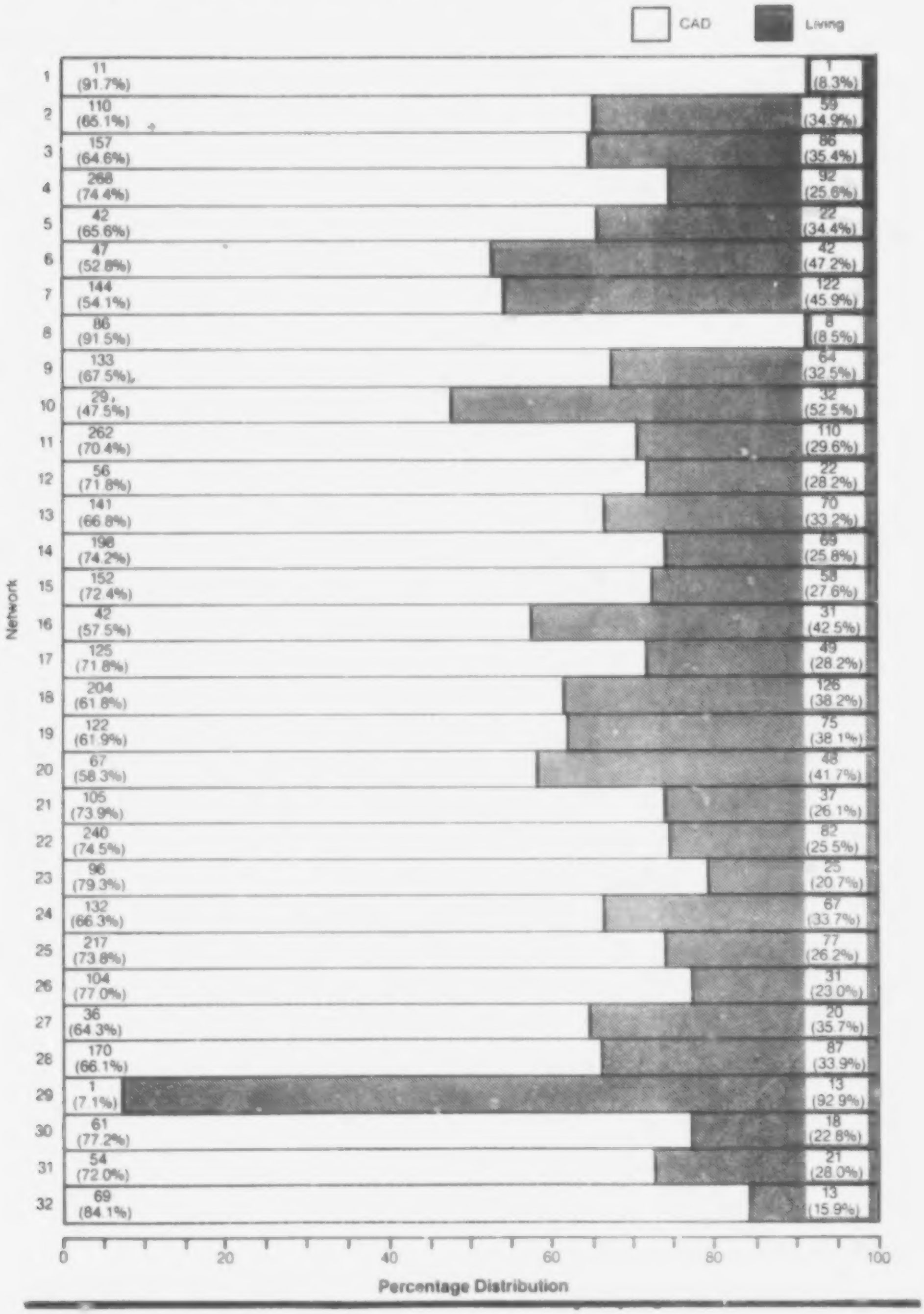
SOURCE: ESRD MEDICAL INFORMATION SYSTEM
1982 FACILITY SURVEYS

Figure 13

C. Number of Transplant Types by Network-1982

Figure 13

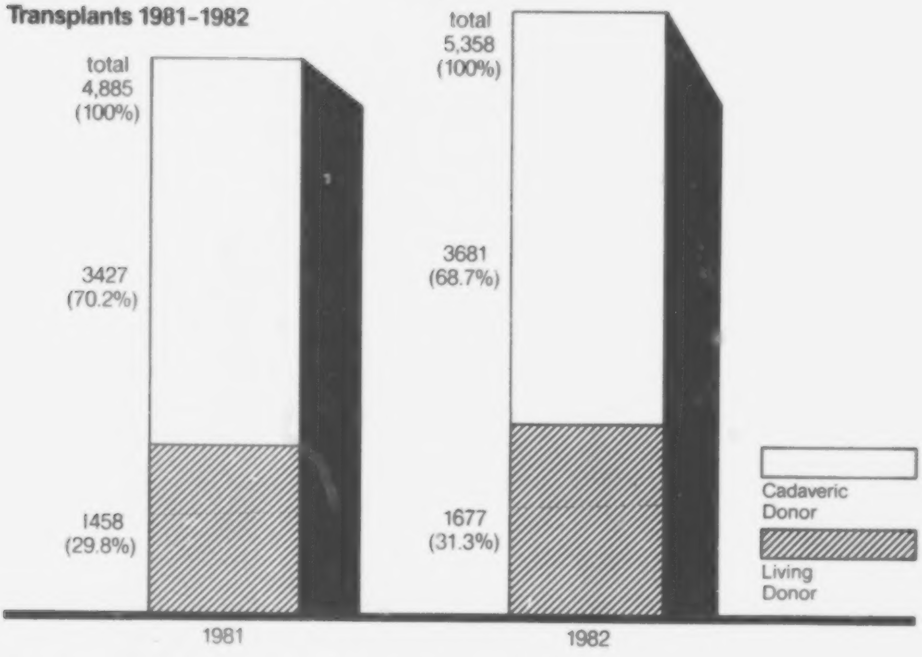
Number Of Transplant Types by Network—1982



SOURCE: ESRD Medical Information System 1982 Facility Surveys

D. Transplants 1981 - 1982

Figure 14



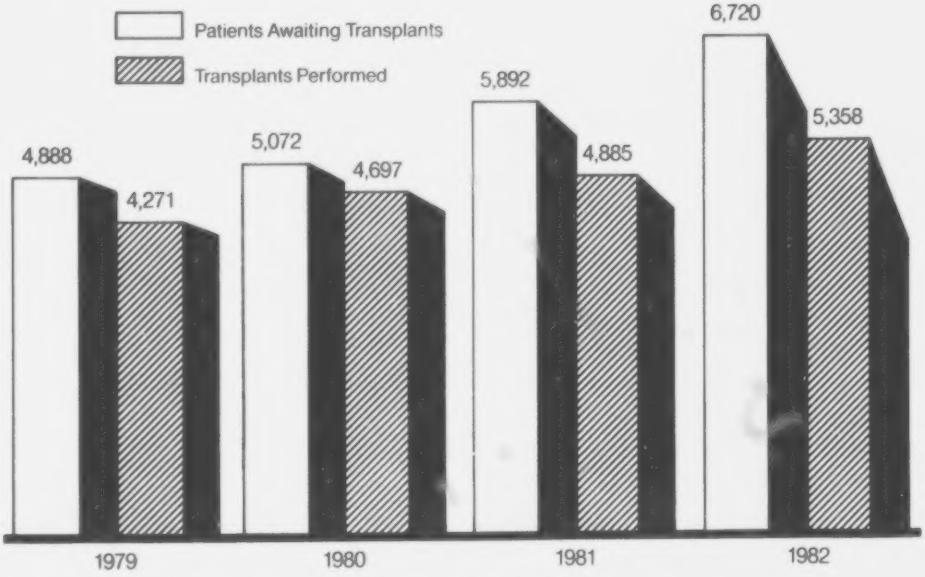
Transplants 1981-1982

SOURCE: ESRD Medical Information System 1981 and 1982 Facility Surveys

E. Patients Awaiting Transplants vs. Transplants Performed

Figure 15

Patients Awaiting Transplants vs. Transplants Performed



SOURCE: ESRD Medical Information System 1979, 1980, 1981 and 1982 Facility Surveys

F. TRANSPLANT FAILURES

Although exact information on the number of transplant failures is not available, information collected by HCFA shows that 1563 patients returned to dialysis from transplantation during 1982. This figure represents 29.3 percent of all patients transplanted in 1982. Comparable figures for 1981 are 1,400 patients, or 28.7 percent of all patients transplanted in 1981.

However, it is important to note that these figures do not present a complete picture of transplant failures. For example, it is impossible to tell from these figures how many years a transplanted graft functioned before failing, since patients returning to dialysis from transplantation in 1982 may have received their transplant several years earlier. Further, data collected from ESRD facilities does not capture transplant failures which resulted in death.

G. Range of the Number of Transplants Performed

The table below shows the range of the number of transplants performed, as reported by the hospitals, for 1982. Table 8 provides a more detailed breakdown.

TABLE 7.

RANGE OF THE NUMBER OF TRANSPLANTS PERFORMED FOR 1982

Range of Number of Transplants Performed	Number of Centers	Percent
0-6	14	9.0
7-14	26	16.7
15-24	34	21.8
25-49	48	30.8
50 or more	34	21.8

TABLE 8.

ESRD NETWORK DISTRIBUTION OF TRANSPLANTS ARRAYED BY NUMBER OF TRANSPLANTS PERFORMED

ESRD NETWORK	FACILITIES SURVEYED & REPORTING	TRANSPLANTS	0	6	7	14	15	24	25	49	50	MORE
1	1	12	0	0.0%	1	100.0%	0	0.0%	0	0.0%	0	0.0%
2	5	169	0	0.0%	1	20.0%	2	40.0%	1	20.0%	1	20.0%
3	2	243	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	100.0%
4	11	360	0	0.0%	3	27.3%	5	45.5%	1	9.1%	2	18.2%
5	2	64	0	0.0%	0	0.0%	1	50.0%	1	50.0%	0	0.0%
6	5	89	2	40.0%	1	20.0%	0	0.0%	2	40.0%	0	0.0%
7	3	266	0	0.0%	0	0.0%	0	0.0%	0	00.0%	3	100.0%
8	2	94	0	0.0%	0	0.0%	0	0.0%	1	50.0%	1	50.0%
9	8	197	1	12.5%	0	0.0%	2	25.0%	5	62.5%	0	0.0%
10	6	61	2	33.3%	2	33.3%	2	33.3%	0	0.0%	0	0.0%
11	8	372	1	12.5%	0	0.0%	1	12.5%	2	25.0%	4	50.0%
12	5	78	2	40.0%	1	20.0%	1	20.0%	1	20.0%	0	0.0%
13	2	211	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	100.0%
14	10	267	2	20.0%	2	20.0%	1	10.0%	3	30.0%	2	20.0%
15	7	210	0	0.0%	1	14.3%	3	42.9%	2	28.6%	1	14.3%
16	2	73	0	0.0%	0	0.0%	1	50.0%	0	0.0%	1	50.0%
17	6	174	0	0.0%	1	16.7%	1	16.7%	4	66.7%	0	0.0%
18	4	330	0	0.0%	0	0.0%	0	0.0%	1	25.0%	3	75.0%
19	4	197	0	0.0%	0	0.0%	0	0.0%	2	50.0%	2	50.0%
20	5	115	2	40.0%	0	0.0%	1	20.0%	2	40.0%	0	0.0%
21	5	142	0	0.0%	1	20.0%	2	40.0%	1	20.0%	1	20.0%
22	6	322	0	0.0%	1	16.7%	0	0.0%	2	33.3%	3	50.0%
23	5	121	0	0.0%	1	20.0%	2	40.0%	2	40.0%	0	0.0%
24	7	199	1	14.3%	1	14.3%	2	28.6%	2	28.6%	1	14.3%
25	7	294	0	0.0%	1	14.3%	2	28.6%	1	14.3%	3	42.9%
26	6	135	1	16.7%	1	16.7%	0	0.0%	4	66.7%	0	0.0%
27	2	56	0	0.0%	1	50.0%	0	0.0%	1	50.0%	0	0.0%
28	9	257	0	0.0%	3	33.3%	2	22.2%	2	22.2%	2	22.2%
29	1	14	0	0.0%	1	100.0%	0	0.0%	0	0.0%	0	0.0%
30	4	79	0	0.0%	1	25.0%	1	25.0%	2	50.0%	0	0.0%
31	3	75	0	0.0%	0	0.0%	2	66.7%	1	33.3%	0	0.0%
32	3	82	0	0.0%	1	33.3%	0	0.0%	2	66.7%	0	0.0%
TOTAL	156	5,358	14	9.0%	26	16.7%	34	21.8%	48	30.8%	34	21.8%
NATIONAL TOTAL				9.0%		25.6%		47.4%		78.2%		100.0%

PERCENTAGES MAY NOT ADD TO 100.0% DUE TO ROUNDING
SOURCE: ESRD MEDICAL INFORMATION SYSTEM 1982 FACILITY SURVEYS

CHAPTER V

COSTS

A. HOSPITALIZATION FOR ANCILLARY PROBLEMS

For the purposes of this report, ancillary hospitalizations were defined as all hospitalizations other than transplants. This is a necessary simplification because many hospitalizations are related to the transplant event, either before the actual transplant or afterward, such as rejection episodes. On average, each transplant patient is hospitalized about three times during the year in which he receives his transplant. However, it is not possible to completely identify which hospital stays are transplant "related". Therefore, the nontransplant stays of transplant patients are considerd to be ancillary hospitalizations.

Data

The basic data were taken from the 1980 Medpar* 20 percent sample of hospital stays. This sample of stays includes procedure coding so it was possible to determine average charges and length of stay for transplant and nontransplant stays. The 1980 MEDPAR contained a slight shortfall (about one percent) at the time of this analysis. Thus the figures were adjusted upward to approximate costs for 100 percent of stays. Hospital covered charges and covered days of care were estimated directly from the MEDPAR records.

Program costs in the form of actual Medicare reimbursements were calculated by taking the national Medicare reimbursement to charges ratio and applying it to these discharges.

Results

Table 9 summarizes the results of this analysis. In 1980, Medicare ESRD patients had a total of 97,023 discharges. Of the total discharges, 59 percent were nonsurgical, 36 percent included a surgical procedure other than transplant, and 4 percent were for transplants.

Inpatient charges amount to over $475 million for this population. Because of the relatively high cost of transplant stays, one-fifth (21 percent) of all inpatient charges were for transplant stays. Overall, the average charge per stay for the ESRD population in 1980, was $4,904. The average transplant stay had a charge of $24,188 while the average ancillary (i.e., nontransplant) hospital stay had a charge of $4026. Of the total ancillary stays, the average charge for nonsurgical stays was $2,572 and the average charge for surgical stays was $6,398.

---

*Medicare Provider Analysis and Review File, which is a random 20 percent sample of all inpatient discharges. It includes diagnostic and procedure coding.

Medicare reimbursements are not equal to hospital charges. Applying the national ratio of Medicare reimbursements to charges gives an estimate of the costs to Medicare for ESRD hospitalization. In 1980 the cost to charges ratio was .696. That is, Medicare paid hospitals an average of 69.6 percent of charges. An exception to this are kidney acquisition costs which are reimbursed at 100 percent. For all ESRD patients, estimated Medicare inpatient hospital payments were $342 million; $82 million were for transplants and $260 million for nontransplant (or ancillary) stays.

As noted earlier, nonsurgical stays comprised 59 percent of all stays while the nontransplant surgical stays were 36 percent of the total. However, due to the higher costs of surgical stays, the nontransplant surgical stays accounted for 59 percent of all nontransplant stay reimbursements (47 percent of all reimbursements). The estimated Medicare reimbursements per stay are $3,520 for all discharges, $19,284 for transplants and $2,802 for all nontransplant stays.

TABLE 9.

CHARGES, ESTIMATED REIMBURSEMENTS AND AVERAGE LENGTH OF STAY FOR TRANSPLANTS AND NONTRANSPLANT HOSPITAL STAYS: 1980

	All Stays	Transplants Stays	Nontransplants Stays		
			All	Non-Surgical	Surgical
Number of Stays	97,023	4,227	92,796	57,548	35,248
Percent	100%	4%	96%	59%	36%
Charges (in 1,000's)	$475,801	$102,243	$373,558	$148,041	$225,517
Percent	100%	21%	79%	31%	47%
Charges Per Stay	$4,904	$24,188	$4,026	$2,572	$6,398
Estimated Reimbursement (1,000's)	$341,536	$81,513	$260,023	$103,064	$156,959
Percent	100%	24%	76%	30%	46%
Estimated Reimbursement Per Stay	$3,520	$19,284	$2,802	$1,791	$4,453
Covered Days	1,120,489	127,655	992,834	566,060	426,774
Percent	100%	11%	89%	51%	38%
Average Length of Stay (Covered Days)	11.5	30.2	10.7	9.8	12.1

Note: Percents may not add to 100 due to rounding.

SOURCE: 1980 MEDPAR 20 PERCENT SAMPLE OF HOSPITAL STAYS

B. KIDNEY ACQUISITION COSTS AND CHARGES

Kidney acquisition services are those services necessary to identify potential donors, maintain a registry of patients awaiting transplant, ensure suitability and compatibility of the selected donor and recipient, excise the donor kidney, transport the organ to the transplant hospital, and maintain the viability of the organ until the time of transplantation. The charges for these services are accumulated and billed to the Medicare program by the hospital which performs the transplant.

The information available on kidney acquisitions is charge data rather than actual cost information. Charge data are received as individual bills and are recorded when the bills are submitted to the intermediary. Cost data are not available until final settlement of each hospital's audited cost report for the fiscal year in question.

In order to determine kidney acquisition charges for 1982, the DHHS Regional Offices requested the intermediaries to provide their transplant hospitals' charges in effect as of December 31, 1982, for living related donor kidneys and cadaveric donor kidneys. This information was provided for 137 transplant hospitals. HCFA compiled the data and found that during 1982, the national average kidney acquisition charge for a living related donor kidney was $9,009, and for cadaveric donor kidneys it was $8,818. The range and average of kidney acquisition charges by DHHS Regions are shown in Tables 10A and 11A.

The intermediaries were also requested to report for each transplant center the cost to charges ratio applicable to the kidney acquisition cost center from the three most recent years for which the ratio was available. Some reported payments based on a percentage of billed charges. HCFA received information from 128 hospitals.

To convert charge data to costs, we multiplied the charge by either the applicable 3-year average cost to charge ratio or by the percent of billed kidney acquisition charges paid to the hospital. The calculations result in an average estimated national kidney acquisition cost for living related donor kidneys of $7,769, and for cadaveric donor kidneys the average estimated cost was $7,636. The range and average of estimated kidney acquisition costs by DHHS Region are shown in Tables 10B and 11B.

It should be noted that the costs derived are based on the arithmetic mean, and are not weighted by the number of transplants performed in each hospital.

TABLE 10A.

KIDNEY ACQUISITION CHARGES AVERAGE AND RANGE FOR LIVING RELATED DONOR KIDNEYS FOR 1982 BY REGION

REGION	HIGH	LOW	AVERAGE
Boston	$11,300	$2,000	$ 6,464
New York	15,000	2,400	8,398
Philadelphia	19,800	5,600	10,301
Atlanta	20,240	4,500	8,434
Chicago	33,000	3,300	9,128
Dallas	14,000	3,000	7,050
Kansas City	23,075	7,000	13,225
Denver	9,946	7,000	8,473
San Francisco	13,550	3,500	9,132
Seattle	14,920	4,500	9,480
National	$17,483	$4,280	$ 9,009

TABLE 10B.

KIDNEY ACQUISITION COSTS AVERAGE AND RANGE OF ESTIMATED COSTS FOR LIVING RELATED DONOR KIDNEYS FOR 1982 BY REGION

REGION	HIGH	LOW	AVERAGE
Boston	$ 9,831	$1,780	$ 5,065
New York	14,631	1,977	6,978
Philadelphia	18,612	4,851	8,202
Atlanta	18,086	3,940	7,649
Chicago	30,030	2,931	8,356
Dallas	11,642	3,563	6,101
Kansas City	22,360	5,766	12,010
Denver	8,990	6,271	7,630
San Francisco	11,803	2,678	7,922
Seattle	11,787	4,137	7,777
National	$15,777	$3,789	$ 7,769

Source: Medicare Fiscal Intermediaries' Reimbursement Files

TABLE 11A.

KIDNEY ACQUISITION CHARGES
AVERAGE AND RANGE FOR CADAVERIC DONOR KIDNEYS FOR 1982 BY REGION

REGION	HIGH	LOW	AVERAGE
Boston	$10,500	$1,950	$ 6,771
New York	15,000	2,400	8,307
Philadelphia	19,800	3,975	9,357
Atlanta	11,165	3,590	7,961
Chicago	30,000	2,400	9,214
Dallas	9,800	1,500	6,659
Kansas City	24,000	7,000	14,698
Denver	8,547	4,100	6,324
San Francisco	13,000	7,100	8,905
Seattle	14,920	7,500	9,980
National	$15,673	$4,152	$ 8,818

TABLE 11B.

KIDNEY ACQUISITION COSTS
AVERAGE AND RANGE OF ESTIMATED COSTS FOR CADAVERIC DONOR KIDNEYS FOR 1982 BY REGION

REGION	HIGH	LOW	AVERAGE
Boston	$ 8,900	$1,346	$ 5,350
New York	14,631	1,977	6,904
Philadelpia	18,612	4,851	7,547
Atlanta	10,780	3,143	7,304
Chicago	27,300	2,388	8,247
Dallas	8,235	3,919	5,863
Kansas City	22,360	5,766	13,287
Denver	7,726	3,673	5,699
San Francisco	10,761	5,226	7,697
Seattle	11,787	7,575	8,464
National	14,109	3,986	7,636

TABLE 12.

1982 KIDNEY ACQUISITION COSTS REPORTED BY INDEPENDENT ORGAN PROCUREMENT AGENCIES BY REGION

REGION	COST PER KIDNEY
Boston	$9,831
New York	1,331*
	6,055
	7,388
Philadelphia	1,787
	6,222
	7,886
Atlanta	0**
	4,040
	5,184
	5,672
	12,157
	13,861
	14,064
Chicago	5,947
	7,078
	8,170**
	8,432
	11,075
Dallas	6,043
	7,216
	7,895
	8,737
Kansas City	6,019
	8,209
	9,236
Denver	0 (no activity)
San Francisco	1,923**
	9,211
Seattle	7,483

*Limited Service OPAS
**First Year of Activity

SOURCE: MEDICARE FISCAL INTERMEDIARIES' REIMBURSEMENT FILES.

C. INDEPENDENT ORGAN PROCUREMENT AGENCIES

Some kidney acquisition services are performed for hospitals by independent organ procurement agencies (OPAs). The services provided differ among OPAs, and range from providing only placement services, to providing all services except medical evaluation of the recipient or any living donors. The costs incurred by an OPA are billed to the transplant hospital and become a component of the hospital's kidney acquisition cost.

Independent OPAs are reimbursed on a cost basis. There are 30 operational OPAs which submitted cost reports during 1982. The cost per kidney for these OPAs ranged from $1331 to $14,064. These figures are cost figures and as such are subject to adjustment on final cost settlement. The cost per kidney varies widely because of the variation in the number of kidney acquisition services performed by the individual OPAs. The data for OPAs was not broken down by type of kidney donor.

Table 12 shows the cost per kidney reported by the OPAs in each of the 10 DHHS Regions. One of the OPAs has been excluded from consideration because it is an umbrella organization, and its member OPAs are included in the data display.

D. DIALYSIS PAYMENT RATES*

The average payment rate for maintenance dialysis in 1982 was estimated to be $156 per treatment (includes all approved reimbursement exception requests). This payment rate reflected the combined weighted average of the payment to each of the two types of ESRD facilities: hospital-based and nonhospital (freestanding). Hospital-based facilities were paid the lesser of their cost or a national payment screen. Their average final reimbursement rate in 1982 was estimated to be $174 per treatment (exclusive of physicians' services). Freestanding facilities were paid the lesser of their charge or a national payment screen. Their average payment (exclusive of physicians' services) was estimated to be $138 per treatment.

On February 12, 1982, the Department of Health and Human Services published a Notice of Proposed Rulemaking (NPRM) in order to implement a change in the law enacted as part of the 1981 Omnibus Budget Reconciliation Act. That Act required that dialysis services be reimbursed under a dual prospective composite rate system. Under this system one rate per treatment would be set per facility so that the same amount would be paid for dialysis performed in the facility and in the patient's home. The rates would be set prospectively based on the relative costs of home dialysis versus infacility dialysis weighted by the percentage of patients dialyzing in each setting. The rates would vary according to the geographical variations experienced in wages across the country, and separate rates would be set for hospital-based facilities versus independent facilities. The average rates that were proposed were $132 per treatment for hospital-based facilities and $128 per treatment for independent facilities. (This NPRM was published as final regulations on May 11, 1983, which were effective for dialysis services performed on or after August 1, 1983. The estimated average payment rates were amended to $131 per treatment for hospital-based facilities and $127 per treatment for independent facilities.)

E. CHANGES IN DIALYSIS RATES

Any ESRD facility desiring a payment rate above the national payment limit must request a reimbursement exception and submit documentation of its higher costs in accordance with instructions set forth in Intermediary Letters 78-9 and 82-1. During 1982, 268 requests for reimbursement exceptions were received.

Of the 268 exception requests received, 17 percent were denied, 1 percent were approved (in full or in part); and 82 percent were returned to the intermediary for further development; i.e., the necessary forms were not properly completed or the documentation submitted was inadequate.

Approval of a rate change depends on the characteristics of an individual facility's patient population. Presently, the most prevalent reasons for approval include the following (but may change as a result of proposed incentive reimbursement regulations):

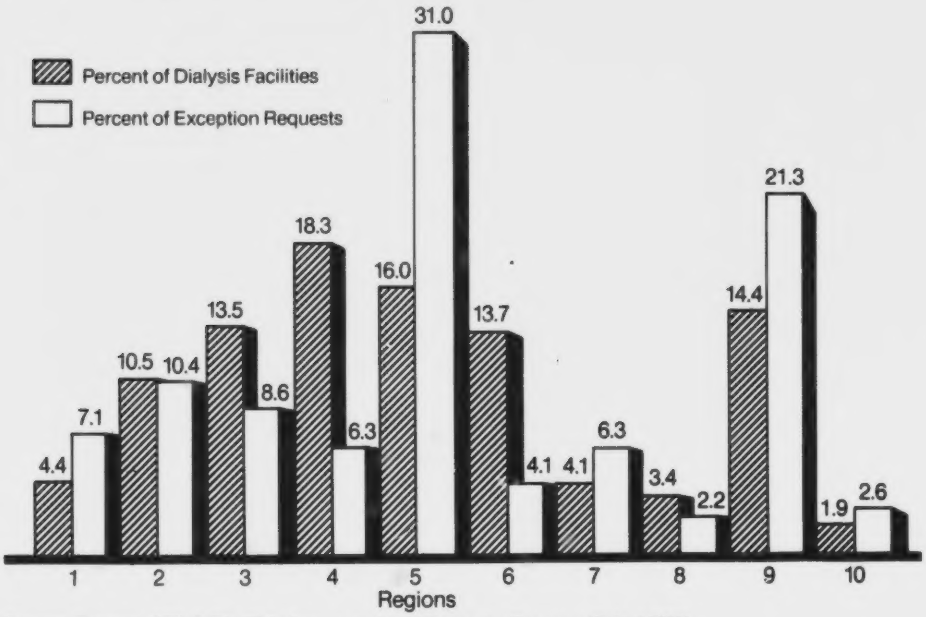
1. Treatment of a more seriously ill patient population than other facilities similarly situated.
2. Treatment of an unusual patient population (e.g., children)

*Data Incomplete

The ranges of exception requests submitted by region are depicted in Figure 16. States with the greatest percentage of facilities requesting exceptions are depicted in Figure 17. Table 13 shows the distribution of exceptions by fiscal year of the facility.

Comparison By Region of Exception Requests - 1982

Figure 16
Comparison By Region Of Exception Requests—1982



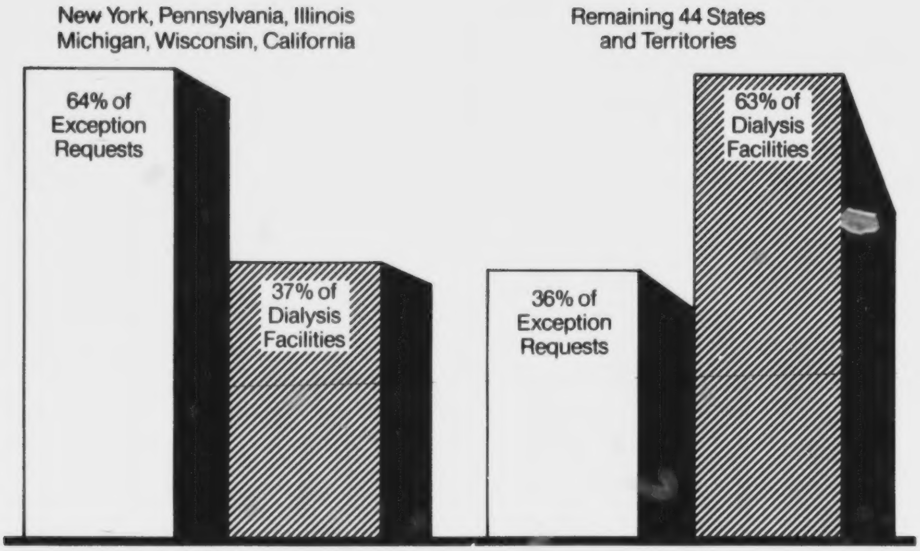
Source: Bureau of Eligibility, Reimbursement and Coverage Program Data, HCFA

READEX FICHE

Comparison By State of Exception Requests - 1982

Figure 17

Comparison By State of Exception Requests—1982



Source: Bureau of Eligibility, Reimbursement and Coverage Program Data, HCFA

TABLE 13.

EXCEPTION REQUESTS PROCESSED IN 1982

For the time period January-December 1982, HCFA processed 268 exception requests with the following breakdown by fiscal year end.

1973 - 1
1974 - 2
1975 - 2
1976 - 3
1977 - 6
1978 - 12
1979 - 37
1980 - 67
1981 - 134
1982 - 4

F. TRANSPLANT PROCEDURES

The estimated 1981 reimbursement per stay for transplants was $21,326. This figure is derived from the Medicare Provider Analysis and Review File, which is a random 20 percent sample of all inpatient discharges. To compute the expenditures for transplant procedures in 1982, we applied the inflation factor for Inpatient Expense per Admission for 1982. Based on unpublished data from the Health Care Financing Administration, the inflation factor for 1982 was 15.5 percent. The resulting cost for a 1982 transplant procedure was $24,632, excluding physicians' services but including the kidney acquisition cost.

G. PHYSICIAN SERVICES

The payment rates for physician services can be categorized by the type of treatment the patient receives, either dialysis or transplant.

Dialysis

In 1982, dialysis physicians were reimbursed under one of two methods—the initial method or the alternative method. Under the initial method, physicians received payment for their supervisory dialysis services directly from the facility, usually under a salary or contract arrangement. Other services required by the patient (not considered routine) were billed to the Medicare program by the physician on a fee-for-service basis.

Under the initial method, the average payment rate to physicians for supervisory services during dialysis was part of the overall dialysis charge billed by the facility. Under the alternative reimbursement method, physicians were paid a monthly fee for each patient for all renal care of that patient. This included supervisory services during dialysis, plus all other renal related services, complicated or routine, furnished during a particular month.

The alternative monthly allowances for physician services to patients dialyzing in a facility ranged from a minimum level of $180 to a maximum level of $260. The allowances for physician services for treatment of patients dialyzing in the home ranged from a minimum level of $126 to a maximum level of $182. The lower payment rates for home dialysis were due to the fewer services rendered to home dialysis patients.

Physician payments are subject to the Supplementary Medical Insurance (Part B) coinsurance, and, thus, Medicare reimbursement is made for 80 percent of the allowed charge.

On February 12, 1982, the Department of Health and Human Services published a Notice of Proposed Rulemaking (NPRM) in response to the 1981 Omnibus Budget Reconciliation Act proposing a change in physician reimbursement. That Act required that physician reimbursement for dialysis be set so as to promote the use of home dialysis. To this end, the Department proposed to pay the same monthly payment to physicians for home dialysis patients and infacility dialysis patients. The rates would vary across the country to reflect local billing practices, and the average proposed monthly payment per patient was $184.

At the same time, the proposed regulation eliminated the initial method of physician reimbursement because that method did not meet the law's requirement of promoting the use of home dialysis. Therefore, all physicians would be paid for their dialysis services under a monthly capitation payment system. (The NPRM was published as final regulations on May 11, 1983, which were effective for dialysis services performed on or after August 1, 1983.)

Transplant

The rules used to determine payment for physicians' renal transplantation services are different from the regular Medicare reasonable charge methodology used to determine payment for physicians' services. Under the regular methodology, the carrier determines the customary charge (generally, the charge most frequently made) by each physician for each separate service furnished to patients in the previous calendar year. The carrier determines the prevailing charge for each covered service. The prevailing charge is the amount which is high enough to cover the customary charges in three out of every four bills submitted in the previous year for each service. Increases in prevailing charges for physicians' services are limited from year to year by an "economic index" formula which relates physicians' fee increases to the actual increases in the cost of maintaining their practices and to raises in general earnings levels.

When a medical insurance claim is submitted, the carrier compares the actual charge shown on the claim with the customary and prevailing charges for that service. The charge approved by the carrier will be either the customary charge, the prevailing charge, or the actual charge, whichever is the lowest.

With respect to renal transplantation services, a comprehensive payment is made for all of the surgeon's services including the usual pre and postoperative surgical care, and for immunosuppressant therapy, when supervised by the attending transplant surgeon, for a period of 60 days. Additional amounts established on the basis of program experience may be included for other surgery performed concurrently with the transplant operation, such as a splenectomy, nephrectomy, or a combination of all of these.

The comprehensive payments are revised July 1 of each year to the extent permitted by the lesser of: (1) changes in the ecomomic index (an increase of 8.88 percent for the period July 1982-June 1983), or (2) changes from one year to the next in the prevailing charges for a unilateral nephrectomy for each of the carrier's localities. The maximum allowances currently allowed by the Medicare Part B carriers for renal transplantation and implantation of graft, including immunosuppressant therapy for 60 days, range from $1734.40 to $2875.

These amounts reflect geographical variations in physician charging practices and would also vary on the basis of whether the surgeon performs other surgical procedures at the time of the renal transplantation.

H. PROJECTED ENROLLMENT AND BENEFIT PAYMENTS FOR THE END-STAGE RENAL DISEASE PROGRAM

Medicare enrollment for persons with ESRD is projected to increase from 80,500 in fiscal year 1984 to about 91,200 by fiscal year 1988. Medicare benefit payments for these persons are projected to increase from $2.1 billion to about $3.1 billion for the same period of time. The year-to-year changes are the result of the interaction of two factors: (1) increases in the population, including changes in the mix of treatment modes, and (2) increases in the cost of services provided. The table below shows the projected enrollment and benefit payments on a cash basis through fiscal year 1988. For the first time, these projections reflect the cost effects of the proposed ESRD regulations (i.e., the dual-composite rate regulation and the ESRD second payer regulation).

TABLE 14.

ESTIMATED ENROLLMENT AND AGGREGATE BENEFIT PAYMENTS ON A CASH BASIS TOTAL ESRD MEDICARE PROGRAM

Fiscal Year	Average Annual Enrollment (thousands)	Total Benefit Payments (millions)
1984	80.5	$2,148
1985	83.7	2,335
1986	86.7	2,567
1987	89.4	2,801
1988	91.2	3,059

In addition, implementation of the ESRD second payer regulation will generate additional income to the Medicare program. We estimate this income to be as shown below.

TABLE 15.

ESTIMATED INCOME TO MEDICARE GENERATED BY ESRD SECOND PAYER REGULATION

Fiscal Year	Income Generated (in millions)
1984	$10
1985	25
1986	35
1987	45
1988	55

SOURCE: OFFICE OF FINANCIAL AND ACTUARIAL ANALYSIS, HCFA

CHAPTER VI

ESRD STATISTICS

TABLE 16.

A. MEDICARE ELIGIBILITY STATUS OF PATIENTS BEING TREATED BY MEDICARE CERTIFIED ESRD FACILITIES

ELIGIBILITY STATUS	DECEMBER 31, 1979	DECEMBER 31, 1980	DECEMBER 31, 1981	DECEMBER 31, 1982
Medicare Eligible	39,333	48,389	51,227	60,197
Pending Medicare	3,342	3,578	3,754	4,182
Non-Medicare	3,531	3,767	3,789	4,216
TOTAL PATIENTS	46,206	55,734	58,770	68,595

SOURCE: ESRD MEDICAL INFORMATION SYSTEM
1979, 1980, 1981, AND 1982 FACILITY SURVEYS

B. VARIATION IN MEDICARE ESRD PROGRAM INCIDENCE BY STATE

This section describes the geographical distribution of new Medicare ESRD enrollees during the years 1978 through 1980. This analysis includes all new Medicare beneficiaries identified as ESRD. Not included in the analysis are non-Medicare ESRD persons, approximately seven percent of the total ESRD population. The term Medicare ESRD program incidence is used to refer to persons with renal failure who receive treatment and Medicare entitlement.

DATA: Counts of persons with ESRD and Medicare entitlement are generated from the Health Insurance Master entitlement records maintained by HCFA. These records provide information on beneficiaries' age, sex, race, entitlement dates and place of residence. Date of renal failure was taken from the Medical Information System records. Population estimates were taken from Census Bureau estimates. The most recent data available which could be broken down by age within race for each State was 1978. Medicare program incidence rates were calculated as new beneficiaries per one million persons in the general population. Rates were averages across three years to give greater stability to the estimates.

RESULTS

Table 17 presents the Medicare ESRD program incidence by State averaged across the years 1978 through 1980. The average number of new Medicare ESRD beneficiaries each year nationwide was 17,035. With a U.S. population of just over 220 million, the Medicare ESRD program incidence rate was 77 per million persons. There was considerable variation by State. Alaska, with 10 new ESRD persons each year had the lowest program incidence at 26 per million. The District of Columbia, with 125 new ESRD persons each year, had the highest program incidence rate at 185 per million.

Part of the State variation rates are due to demographic factors such as age and race. Blacks have incidence rates which are 2.7 times as great as whites. States (and the District of Columbia) with relatively large black populations can be expected to have higher incidence rates. Similarly, age is a strong factor in renal failure with those over 65 having the highest rates. In addition, there appears to be considerable uncertainty about the efficacy of dialyzing elderly patients. This uncertainty could result in differences in medical practice which is neither good nor bad but could result in differing dialysis rates.

In order to control for some of the natural demographic variation across States, the analysis was redone on the white, under age 65 population only. The results are seen on the right side of Table 17. For this population there were, on average, 8,594 new Medicare ESRD beneficiaries each year. The Medicare program incidence rate is 51 per million persons. This adjusted incidence rate removes much of the State variation previously noted. The District of Columbia, which has an overall Medicare program incidence rate of 185 per million, has a rate of 64 per million for whites under age 65. Similarly, Florida's rate changes from 107 per million for all persons to 70 per million for whites under age 65.

The results of this analysis are summarized in Table 18. The aggregate Medicare ESRD program incidence rate spans a wide incidence range across all States. A range of 40 per million (50 per million through 89 per million) is needed to include as many as 38 of the 51 States (and District of Columbia). However, when the analysis is limited to whites under age 65, a range of 20 per million (40 per million through 59 per million) encompasses 41 of the States.

TABLE 17.

Medicare ESRD Program Incidence by State, All Persons and White Over Age 65
1978 to 1980 Average

	ALL PERSONS			WHITE, AGE 0-64		
	1978 Population in 1,000's	Average Annual ESRD Incidence	ESRD Incidence Per Million	1978 Population in 1,000's	Average Annual ESRD Incidence	ESRD Incidence Per Million
Alabama	3742	362.0	97.	2355	152.7	65.
Alaska	403	10.3	26.	257	8.0	31.
Arizona	2354	210.3	89.	1701	125.3	74.
Arkansas	2244	128.3	57.	1446	71.7	50.
California	22294	1830.7	82.	16529	935.7	57.
Colorado	2671	168.3	63.	2165	120.7	56.
Connecticut	3099	217.3	70.	2580	121.7	47.
Delaware	583	48.3	83.	444	25.3	57.
Washington D.C.	674	125.0	185.	152	9.7	64.
Florida	8594	921.0	107.	5457	381.7	70.
Georgia	5084	482.0	95.	3256	178.3	55.
Hawaii	897	86.7	97.	307	17.0	55.
Idaho	878	38.3	44.	684	29.3	43.
Illinois	11243	807.3	72.	8585	402.7	47.
Indiana	5374	325.3	61.	4416	205.0	46.
Iowa	2915	155.3	53.	2460	116.0	47.
Kansas	2348	118.3	50.	1873	72.7	39.
Kentucky	3518	197.7	56.	2748	124.3	45.
Louisana	3966	326.7	82.	2377	107.7	45.
Maine	1091	46.3	42.	910	35.3	39.
Maryland	4143	315.7	76.	2986	128.3	43.
Massachusetts	5774	405.0	70.	4927	225.3	46.
Michigan	9189	627.7	68.	7247	304.0	42.
Minnesota	4047	235.3	58.	3394	137.7	41.
Mississippi	2404	195.3	81.	1309	62.0	47.
Missouri	4880	302.0	62.	3716	166.0	45.
Montana	785	36.0	46.	623	25.3	41.
Nebraska	1585	91.0	57.	1288	64.0	50.
Nevada	663	59.3	89.	470	35.3	75.
New Hamphsire	871	44.0	51.	703	30.7	44.
New Jersey	7327	709.3	97.	5748	332.7	58.
New Mexico	1212	96.7	80.	913	54.7	60.
New York	17748	1457.3	82.	13842	665.0	48.
North Carolina	5577	455.3	82.	3712	180.0	48.
North Dakota	652	33.7	52.	544	25.0	46.
Ohio	10749	710.0	66.	8731	418.7	48.
Oklahoma	2880	189.0	66.	2072	111.3	54.
Oregon	2444	118.0	48.	1913	87.7	46.
Pennsylvania	11750	938.7	80.	9519	514.0	54.
Rhode Island	935	78.3	84.	828	42.3	51.
South Carolina	2918	237.7	81.	1722	80.7	47.
South Dakota	690	36.7	53.	557	22.7	41.
Tennessee	4358	305.7	70.	3082	156.3	51.
Texas	13092	1053.3	80.	9326	540.0	58.
Utah	1308	69.0	53.	1039	53.7	52.
Vermont	487	28.3	58.	413	19.7	48.
Virginia	5150	481.0	93.	3591	193.7	54.
Washington	3774	217.7	58.	2945	149.7	51.
West Virginia	1860	113.0	61.	1518	79.0	52.
Wisconsin	4679	295.7	63.	3877	196.3	51.
Wyoming	424	15.3	36.	311	10.7	34.
U.S. Total	202,276	17,035.3	77.	168,088	8,593.7	51.

SOURCE: ESRD MEDICAL INFORMATION SYSTEM ENTITLEMENT RECORDS - 1978, 1979, and 1980.

TABLE 18. MEDICARE PROGRAM INCIDENCE RATES, BY STATE DISTRIBUTION: 1978-1980

	Number of States	
Rate Per Million	All Persons	White Age 0-64
20-29	1	0
30-39	1	4
40-49	4	23
50-59	12	18
60-69	8	3
70-79	5	3
80-89	13	0
90-99	5	0
100+	2	0
TOTAL	51	51

U.S. Total:

All Persons = 77 Per Million
White, 0-64 = 51 Per Million

SOURCE: ESRD MEDICAL INFORMATION SYSTEM
ENTITLEMENT RECORDS - 1978, 1979, AND 1980

C. MORTALITY AND SURVIVAL RATES

For dialysis patients, the overall mortality rate was 131 per 1,000 dialysis patients per year (shown in Table 19). The age-adjusted rates were similar among white females, non-white males and non-white females; in comparison, white males had a slightly higher mortality rate (10-13 percent higher). The modified life table analysis for dialysis patients (Table 20) suggests that survival is poorest in the first year of entry into the ESRD Program (relative survival = 81 percent) (as in the analyses for the previous Annual Report, the first year of survival is conditional upon having survived for 3 months from first ESRD treatment to entry into these calculations). For each successive year-after-entry the survival improved 1 to 2 percent. The overall 7-year cumulative relative survival rate for the dialysis patients was 30 percent. This was similar between the race-sex groups, with some slight differences in the same direction as the mortality rates: survival among non-whites was slightly better than for whites, and for white males it was slightly worse than for white females.

For the analyses of transplant patients, the date of entry for each patient was the date of renal transplantation. The date of exit for these analyses was the date of death, the loss of entitlement, the date of transplant failure plus 90 days, or September 30, 1981, whichever came first. The overall mortality rate for the transplant patients was 113 per 1,000 transplant patients per year (shown in Table 21). Since the rates for non-whites were based upon small numbers, caution is recommended in drawing conclusions since such rates are less "stable" than those based on larger numbers. The age-adjusted rates suggest that white males have a somewhat higher mortality rate than non-white males, while the opposite may be seen for women. The modified life table analysis for transplant patients (Table 22) suggests that survival improved approximately 10 percent in the second year as compared to the first year.

The overall cumulative relative survival rate for the transplant patients was 82 percent. This was similar between the sex groups. Non-whites had a slightly lower cumulative relative survival rate as compared to whites.

Table 19. Mortality rates (per 1,000 ESRD dialysis patients, per year) for the dialysis study population whose date of first reported dialysis was 9/73 or later, followed to death, transplant, or 9/81, by age, race, and sex, and adjusted* for these factors.

Age	White Male (56453)**	White Female (46050)	Non-White Male (25620)	Non-White Female (24088)	Total (152211)
less than 20	63.3	64.1	64.4	81.6	65.6
20-24	75.4	90.4	76.7	87.6	81.6
25-29	104.9	105.7	85.4	98.3	100.2
30-34	132.4	120.4	99.1	99.1	117.5
35-39	146.8	130.3	110.8	102.7	127.8
40-44	156.6	126.8	119.1	110.4	132.0
45-49	170.8	142.5	147.0	123.9	149.3
50-54	182.0	151.3	167.0	153.4	164.4
55-59	212.0	180.6	190.5	176.8	192.3
60-64	247.7	210.7	231.8	196.7	225.4
65-69	310.2	275.3	274.8	263.9	287.7
70-74	381.3	309.2	323.1	302.9	340.4
75+	490.8	444.3	443.9	347.5	454.2
Total	228.3	193.9	178.5	174.3	
Age-Adjusted	142.1	128.9	126.7	125.2	
Age, Race and Sex Adjusted					130.4

---

*Adjusted to the total U.S. population in 1970.

**Total number of person-years included.

Table 20. Modified life table analyses for the dialysis study population whose first dialysis was 9/73 or after (Follow-up is to death, transplant, or 9/81).

	Interval (yr)*	LX**	Deaths	Survival***	Survival****
Total	0	78786	13995	0.80 (0.81)	0.80 (0.81)
	1	48578	7739	0.82 (0.83)	0.66 (0.68)
	2	29853	4316	0.84 (0.85)	0.55 (0.57)
	3	18160	2352	0.85 (0.86)	0.47 (0.49)
	4	10886	1265	0.86 (0.87)	0.40 (0.43)
	5	5922	607	0.87 (0.88)	0.35 (0.38)
	6	2860	265	0.87 (0.88)	0.30 (0.33)
	7	907	54	0.89 (0.90)	0.27 (0.30)
White Males	0	31010	6016	0.78 (0.80)	0.78 (0.80)
	1	18308	3277	0.80 (0.81)	0.62 (0.65)
	2	10908	1821	0.81 (0.82)	0.51 (0.53)
	3	6459	945	0.83 (0.85)	0.42 (0.45)
	4	3779	486	0.85 (0.86)	0.36 (0.39)
	5	2013	228	0.86 (0.87)	0.30 (0.34)
	6	953	99	0.85 (0.87)	0.26 (0.29)
	7	313	17	0.90 (0.91)	0.23 (0.26)
White Females	0	23656	4187	0.80 (0.81)	0.80 (0.81)
	1	14523	2219	0.82 (0.84)	0.66 (0.68)
	2	9089	1234	0.85 (0.85)	0.56 (0.58)
	3	5597	671	0.86 (0.87)	0.48 (0.50)
	4	3370	354	0.87 (0.88)	0.42 (0.44)
	5	1847	173	0.88 (0.89)	0.37 (0.39)
	6	888	73	0.88 (0.89)	0.33 (0.35)
	7	289	20	0.87 (0.88)	0.29 (0.30)

SOURCE: NIH, National Cancer Institute

Table 20(Cont.)

	Interval (yr)*	LX**	Deaths	Survival***	Survival****
Non-White Males	0	12655	1979	0.83 (0.84)	0.83 (0.84)
	1	8124	1175	0.84 (0.85)	0.69 (0.72)
	2	5054	643	0.85 (0.87)	0.59 (0.62)
	3	3135	400	0.85 (0.87)	0.50 (0.54)
	4	1908	223	0.86 (0.87)	0.43 (0.47)
	5	1031	103	0.87 (0.89)	0.38 (0.42)
	6	500	38	0.89 (0.90)	0.34 (0.38)
	7	172	13	0.86 (0.87)	0.29 (0.33)
Non-White Females	0	11465	1813	0.83 (0.84)	0.83 (0.84)
	1	7623	1068	0.84 (0.85)	0.70 (0.71)
	2	4802	618	0.85 (0.86)	0.59 (0.62)
	3	2969	336	0.87 (0.88)	0.52 (0.54)
	4	1829	202	0.87 (0.88)	0.45 (0.47)
	5	1031	103	0.88 (0.88)	0.39 (0.42)
	6	519	55	0.84 (0.85)	0.33 (0.36)
	7	133	4	0.94 (0.95)	0.31 (0.34)

---

*Interval from date of entry into analysis.

**Number of patients alive at the start of the specified interval.

***Crude and relative survival rates for each interval. Relative survival rates given in parentheses.

****Cumulative crude and relative survival rates by interval from date of entry. Relative survival rates given in parentheses.

Table 21. Mortality rates (per 1,000 ESRD transplant patients, per year) for the renal transplantation population whose date of first reported transplant was 7/73 or later, followed to death, date of transplant failure plus 3 months, termination of entitlement, or 9/81, by age, race, and sex, and adjusted* for these factors.

Age	White Male (11076)**	White Female (7532)	Non-White Male (2864)	Non-White Female (1480)	Total (22952)
less than 20	54.2	45.8	52.3	106.8	53.2
20-24	54.7	43.2	79.5	40.1	52.2
25-29	53.1	63.6	74.7	95.5	61.8
30-34	71.5	79.1	71.5	154.4	79.4
35-39	106.3	108.2	124.8	110.6	110.0
40-44	107.9	108.0	151.3	149.3	118.8
45-49	177.5	138.1	218.6	178.6	172.5
50-54	178.9	169.1	162.8	203.9	175.7
55-59	198.3	155.3	241.4	197.0	188.8
60-64	223.2	90.9	243.9		197.5
65-69	257.1	94.3***		678.0***	173.6
70-74	129.9***	202.0***	83.3***		141.5***
75+	800.0***	-0-***			224.7***
Total	99.6	86.4	123.2	131.8	
Age-Adjusted	126.6	79.4	99.3	147.4	
Age, Race and Sex Adjusted					113.2

---

*Adjusted to the total U.S. population in 1970.
**Total number of person-years included.
***Rate based upon 5 or fewer deaths.

Table 22. Modified life table analyses for the renal transplantation population whose first transplant was 7/73 or after (Follow-up is to death, date of transplant failure plus 3 months, termination of entitlement, or 9/81, whichever occurred first).

	Interval (yr)*	LX**	Deaths	Survival***	Survival****
Total	0	18590	1968	0.88 (0.88)	0.88 (0.88)
	1	11943	218	0.97 (0.97)	0.86 (0.86)
	2	3888	116	0.96 (0.96)	0.82 (0.82)
White Males	0	8897	935	0.88 (0.88)	0.88 (0.88)
	1	5737	115	0.97 (0.97)	0.85 (0.86)
	2	1902	53	0.96 (0.97)	0.82 (0.83)
White Females	0	5884	567	0.89 (0.89)	0.89 (0.89)
	1	3995	53	0.98 (0.98)	0.87 (0.88)
	2	1317	31	0.97 (0.97)	0.85 (0.85)
Non-White Males	0	2515	296	0.86 (0.89)	0.86 (0.87)
	1	1432	32	0.97 (0.97)	0.83 (0.84)
	2	445	25	0.93 (0.93)	0.77 (0.78)
Non-White Females	0	1294	170	0.85 (0.85)	0.85 (0.85)
	1	779	18	0.96 (0.97)	0.82 (0.82)
	2	224	7	0.96 (0.96)	0.78 (0.79)

---

*Interval from date of entry into analysis.

**Number of patients alive at the start of the specified interval.

***Crude and relative survival rates for each interval. Relative survival rates given in parentheses.

****Cumulative crude and relative survival rates by interval from date of entry. Relative survival rates given in parentheses.

SOURCE: NIH, National Cancer Institute

D. MORTALITY AND GRAFT FAILURE RATES

Survival rates and rates of graft retention for patients who had begun dialysis or who had received transplants between January 1, 1977 and December 31, 1980 have been determined from the data collected by the Medical Information System (MIS) of the Health Care Financing Administration covering nearly all persons with end-stage renal disease in the United States.

The salient observations are: (1) Transplants performed in successive years in the period 1977-1980 show progressive and substantial increases in the rates of graft retention, while survival rates for both dialysis patients and transplant recipients have remained stable. (2) Transplant recipients are subject initially to high risks of loss of graft and of death, but these risks decrease rapidly in the few months following transplantation. The dialysis population is subject to a nearly constant death rate which is generally higher than the stable late mortality rate of transplant recipients. (3) Blacks have higher survival rates than whites on dialysis, similar survival rates following transplantation, and inferior rates of retention of functioning grafts. (4) Best results are obtained in recipients of kidneys from related donors.

The utility of the national data is, at present, limited by the incomplete reporting of medical information by the centers providing treatment. Thus, data on the many factors that may underlie selection of a treatment mode or the different experiences of demographic subgroups are not available. Efforts are currently underway to remedy this deficiency.

The Data Base

As of March 1982, 132,315 patients were described on the MIS computer files. Persons on whom data were collected include all those who became eligible for support through Social Security between July 1973 and March 1982 and who received treatment at certified facilities. Enrollment occurs at the time of transplantation or three months following initiation of chronic dialysis, except for persons who had previously become entitled to Medicare support, such as those over 65 years of age, and are, therefore, not subject to the waiting period.

The patient records were constructed from the primary forms completed by the staff of centers providing care and verified by the ESRD Networks serving these centers. The date of first dialysis was obtained from the patient history form or was calculated from reimbursement data. Transplant dates were determined in this manner for 66 % of the persons identified in the facility surveys as having received a transplant in 1977 or thereafter. The reason for this was the failure of certain centers to submit the medical data forms, in contrast to the forms required for reimbursement. The date of graft rejection was the date of death, the date of transplant nephrectomy, the date of retransplantation, or the date of return to chronic dialysis, whichever came first. A transplant recipient was adjudged to have returned to chronic dialysis upon having been subjected to 12 or more dialysis sessions in one continuous treatment period or in two consecutive periods separated by less than 30 days. The date of graft rejection in such cases was defined as the date on which dialyses were begun. An alternate criterion of 26 dialysis sessions in a quarter gave essentially similar results with some reallocation among the return to chronic dialysis and other failure modes. Patients were followed so long as they continued to receive benefits under the ESRD program of the HCFA. The term of eligibility for recipients of functioning grafts is three years. Approximately 1.5 percent of the persons on dialysis are lost to follow-up annually.

Demographic data (age, race, sex) are available on virtually all persons in the files, and so is the date of death if death occurred.

Analytic Methods

Mortality and graft failure rates for persons who began dialysis or were transplanted between January 1, 1977 and Decemnber 31, 1980 were determined by the method of Cutler and Ederer (3), as implemented by the BMDP Statistical Software (UCLA). The dialysis and transplant populations were contemporaneous and had at least one year of follow-up. Persons identified as having received a transplant were included in the analysis of mortality on dialysis but were held at risk only until the time of transplantation. It should be noted that the 73 % of dialysis patients who were under 65 years of age became eligible for reimbursement of costs by the HCFA and, therefore, appeared on the data files three months after entry on chronic dialysis. Recipients of transplants are eligible for benefits immediately. Graft survival rates were calculated for each transplant received. For the calculation of mortality rates of the transplanted population, the beginning date was the date of the transplant. If the graft was rejected and the patient returned to dialysis, a death occurring within 90 days of the rejection was still charged to the transplant. If death did not occur, the patient ceased to be held at risk; i.e., was censored from the analysis, at the end of this interval. The terminal date was the date of failure (rejection or death), or the date of the last recorded transaction pertaining to the patient.

Results

Table 23 summarizes the pattern of survival of ESRD patients treated by dialysis or by transplantation of a kidney from a related living donor or an unrelated cadaveric donor, and Table 24 the pattern of retention of functioning grafts (graft survival) obtained from the two types of donors. The national data thus confirm the well-known superior outcomes of grafts from related donors. In the aggregate, persons on dialysis suffer a higher mortality rate than transplant recipients, a difference that is accentuated at longer times. Thus, although the dialysis population has a nearly constant risk of death of about 19% per year at least for the first four years after initiation of treatment, the death rate even for recipients of cadaveric transplants is 14% in the first post-transplant year and 4% in the third year. However, comparison of the same age groups within the dialysis and cadaveric-donor transplant populations reveals a much more heterogeneous pattern. Short term (1 year) survival appears to be generally superior on dialysis, very distinctly so for the 31-50 year olds, while longer term (3 year) survival tends to be superior for transplant recipients over 20 years of age. The oldest age groups with the highest mortality rates are highly disproportionately represented in the dialysis population, two-thirds of which is over 50 years old, whereas only one-eighth of the transplant population falls in that category.

As has been noted previously (4), the incidence of ESRD in blacks is out of proportion to their frequency in the U.S. population by a factor of nearly three. Blacks suffer lower death rates than whites on dialysis, and comparable ones after transplantation. Women constitute a slightly smaller proportion of the transplanted than of the overall ESRD population. The survival experience of the two sexes is quite similar.

The association of demographic characteristics with rates of graft failure is shown in Table 24. These rates are distinctly higher in blacks than in whites, whether the donor is related or unrelated. The progressively poorer performance with increasing age is more marked in the case of living, related donor than in cadaveric donor transplants. The stability of survival rates for persons first receiving treatment in successive years beginning in 1977 is shown in Table 25. In contrast, Table 26 displays the steady and statistically significant (P .00001) improvement in graft survival for both related and unrelated donor transplants performed in the years 1977-1980.

Discussion

The Medical Information System of the Health Care Financing Administration maintains records on all recipients of Medicare benefits for end-stage renal disease. This includes about 93% of the U.S. population with ESRD. The data contained thereon describing age, race, sex and date of death are reliable. The date on which chronic dialysis began, if not specified on the patient history form, is readily reconstructed with adequate accuracy from the financial records. The definitions of the date of transplantation and the date of graft rejection are somewhat more tenuous because of imperfect, though improving, compliance with the requirement to complete the medical data forms.

Confidence in the results of the graft survival analyses is strengthened by their consistency with results obtained in other studies covering similar time periods (1,2,5,6). The very encouraging trend in improvement in rates of retention of grafts implanted in successive years following 1977 has also been noted elsewhere (7).

At this time, more detailed analysis of the MIS data is impeded by the incompleteness of the medical information. However, substantial efforts are underway consisting of the devising of new forms, the institution of additional incentives for their timely completion and submission, and the enlisting of the more enthusiastic participation of the professional communities. It may, therefore, be reasonably expected that additional useful information on dialysis and transplantation as treatments of end-stage renal disease will be forthcoming.

REFERENCES

1. Perdue ST and Terasaki, PI. Analysis of interracial variation in kidney transplant and patient survival. Transplantation. 1982; 34:75-77.

2. McDonald JC, Vaughn WK, Filo RS, et al. Cadaver donor renal transplantation by Centers of the South-Eastern Organ Procurement Foundation. Ann. Surg. 1981; 193:1-6.

3. Cutler SJ and Ederer F. Maximum utilization of the life table method in analyzing survival. J. Chron. Dis. 1958; 8:699-713.

4. Rostand SG, Kirk KA, Rutsky EA and Pete BA. Racial differences in the incidence of treatment for end-stage renal disease. N Engl J Med. 1982; 306:1276-1279.

5. Krakauer H, Spees EK, Vaughn WK, et al. Assessment of prognostic factors and projection of outcomes in renal transplantation. Transplantation, in press.

6. Krakauer, H. The kidney transplant histocompatibility study. Analysis of the data. Phase one: an overview. NIH publication no. 80-2164. Washington, DC, US Printing Office, 1980.

7. Terasaki PI, Opelz G and Mickey MR. Clinical kidney transplants. Cell Immunol 1981; 62:277-286.

Table 23. Patient Survival Rates for the Various Demographic Categories

Category	Dialysis			Transplantation					
				Unrelated Donor Transplants			Related Donor Transplants		
Percent Surviving to:	1 Year	3 Years	Cases[1] Entered	1 Year	3 Years	Cases[1] Entered	1 Year	3 Years	Cases[1] Entered
Overall	81±.2%	56±.3%	65,270	86±.4%	78±.5%	7595	95±.4%	91±.6%	3491
Male	81±.3	55±.4	36,600	86±.6	77±1	4818	95±.5	90±1	2079
Female	82±.4	58±.4	28,581	86±1	78±1	2777	94±.6	91±1	1410
			65,181			7595			3489
Black	85±.3	62±.5	17,194	86±1	78±1	1625	93±1	87±2	364
White	80±.2	54±.3	43,990	86±.5	77±1	5588	95±.4	91±1	2905
			61,184			7213			3269
Age=0-10 yrs	90±2	82±3	601	89±3	80±3	155	93±2	89±3	150
11-20	95±.5	88±2	2,620	92±1	87±1	844	97±1	95±1	662
21-30	91±.5	78±1	6,240	92±1	87±1	1792	97±1	95±1	1180
31-40	89±.5	71±1	7,883	85±1	78±1	2016	93±1	89±1	798
41-50	88±.4	68±.7	9,995	81±1	70±1	1737	91±1	82±2	490
Over 50	77±.2	48±.3	35,911	79±1	68±2	1051	88±2	81±3	208
			63,250			7595			3488

---

[1] The discrepancies in the totals are the result of exclusion of cases with missing data. In addition, results for the small, heterogeneous group of persons other than black or white are not shown.

The uncertainties are standard errors.
SOURCE: NIH, National Institute of Allergy and Infectious Diseases

Table 24. Graft Retention Rates for the Various Demographic Categories

Category	Unrelated Donor Transplants			Related Donor Transplants		
Percent Retained to:	1 Year	3 Years	Cases[1] Entered	1 Year	3 Years	Cases[1] Entered
Overall	56+1%	45+1%	7591	75+1%	67+1%	3489
Male	55+1	44+1	4808	74+1	65+1	2076
Female	58+1	46+1	2776	78+1	71+1	1409
			7584			3485
Black	50±1	37±1	1624	64±3	55±3	364
White	58±1	47±1	5578	79±1	69±1	2901
			7202			3265
Age=0-10 yrs	58±4	46±4	155	80±3	71±4	149
11-20	59±2	46±2	843	77±2	68±2	662
21-30	59±1	48±1	1790	79±1	72±1	1179
31-40	56±1	44±1	2010	74±2	66±2	797
41-50	54±1	42±1	1737	69±2	58±2	490
Over 50	52±1	41±1	1049	68±3	60±3	207
			7584			3484

[1] The discrepancies in the totals are the result of exclusion of cases with missing data. In addition, results for the small, heterogeneous group of persons other than black or white are not shown.

The uncertainties are standard errors.
SOURCE: NIH, National Institute of Allergy and Infectious Diseases

Table 25. Patient Survival Rates by Year of Onset of Treatment

Category	Dialysis			Transplantation					
				Unrelated Donor Transplants			Related Donor Transplants		
Percent Surviving to:	1 Year	3 Years	Cases Entered	1 Year	3 Years	Cases Entered	1 Year	3 Years	Cases Entered
1977	82±.3%	57±.5%	16,501	87±1%	79±1%	1203	94±1%	89±1%	857
1978	82±.5	54±.5	14,301	84±1	75±1	1849	94±1	89±1	944
1979	81±.3	55±.5	16,605	85±1	77±1	2151	95±1	92±1	895
1980	81±.3	—	17,863	87±1	—	2399	95±1	—	797

The uncertainties are standard errors.

SOURCE: NIH, National Institute of Allergy and Infectious Diseases

Table 26. Graft Retention Rates by Year of Transplantation

Category	Unrelated Donor Transplants			Related Donor Transplants		
Percent Retained to:	1 Year	3 Years	Cases Entered	1 Year	3 Years	Cases Entered
1977	52±1%	40±1%	1202	70±2%	61±2%	857
1978	53±1	41±1	1845	73±1	63±2	940
1979	56±1	45±1	2149	76±1	69±2	895
1980	61±1	—	2395	82±1	—	797

The uncertainties are standard errors.

SOURCE: NIH, National Institute of Allergy and Infectious Diseases

E. INPATIENT UTILIZATION

The number of inpatient hospital admissions and the days of inpatient care utilized can be used as an indicator of the relative success of medical management of patients with end-stage renal disease. Since the data include admissions for all reasons, they are not a specific measure of morbidity, but they are a rough measure of overall health.

The data were gathered from hospital bills posted as of March 10, 1983. Excluded from the tables are data on individuals who were still patients as of January 1, 1982; that is, the tables reflect data only from patients whose inpatient stay ended on or before December 31, 1981.

RESULTS

Table 27 presents the distribution of ESRD persons by number of hospitalizations for 1980 and 1981. The number of ESRD persons at risk of hospitalization was 57,814 in 1980 and 64,059 in 1981. These are enrollment counts as of July 1 each year. The distribution of hospitalized persons remained essentially unchanged from 1980 to 1981. In 1980, 28 percent of ESRD persons were not hospitalized. In 1981 the percent of non-hospitalized persons rose to 30 percent. In both years 30 percent of persons were hospitalized once and seven percent were hospitalized five or more times.

Table 28 presents hospitalization data expressed in rates per 1,000 ESRD beneficiaries. Discharge rates, days of care rates and average length of stay are presented for 1980 and 1981 by age, sex and race. In 1981, ESRD patients accounted for 105,890 discharges and 1,197,303 days of care. This resulted in 1,653 discharges per 1,000 ESRD persons and 18,691 days of care per 1,000 ESRD persons. The average length of stay per hospitalization was 11.3 days. The two age categories with the highest hospitalization rates were the 0-24 year olds and the 65 and over group (20,243 days per 1,000 persons and 20,368 days of care per 1,000 persons, respectively). The days of care for females of 19,747/1,000 was 11 percent higher than the male rate of 17,822/1,000. Race also affected hospitalization. Whites had the highest days of care rate at 19,116/1,000. Blacks were next with 18,360/1,000 and other/unknown had a days of care rate of 15,363/1,000.

There was a very slight decline in hospitalization from 1980 to 1981. Overall, both discharge rates and average length of stay declined by 2 percent for a net decline in the days of care rate of about 4 percent. This modest decline occurred for all subgroups except the 0-24 year old age group which experienced a three percent increase in the days of care rate.

Table 29 presents the same hospitalization data after omitting persons transplanted in 1980 and 1981. There were 3,918 Medicare transplants in 1980 and 4,073 in 1981. They accounted for 187,000 days of care in 1980 and 194,000 days of care in 1981. The impact of these patients on the hospitalization rates varies considerably. In 1981 22 percent of persons aged 0-24 received transplants. The proportions of persons receiving transplants in the 25-44, 45-64, and 65 and over age groups were 12 percent, 4 percent and less than 1 percent, respectively.

Table 29 thus presents the estimated hospitalization experience for dialysis patients only. Overall in 1981, there is an eleven percent change in days of care per 1,000 (18,691 in table 28 and 16,718 in table 29). The deletion of transplant patients and their associated hospitalizations causes a clear age relationship to appear. Non-transplant persons aged 0-24 had 12,848 days of care/1,000. Those persons in the next three age groups had 13,947 days of care/1,000, 16,677 days of care/1,000 and 20,351 days of care/1,000, respectively. Females had 17 percent more days of care than males (18,183/1,000 and 15,490/1,000 respectively). The removal of transplants changes the race relationship somewhat. In 1981 seven percent of whites received transplants and four percent of blacks. Among the remaining patients blacks had a days of care rate which was one percent higher than whites (17,018/1,000 and 16,895/1,000 respectively. The change in hospitalization from the previous year was similar to that shown in Table 28. Overall, there was a three percent decline in the days of care rate (17,320/1,000 in 1980 and 16,718/1,000 in 1981). Each subgroup experienced a decline in the days of care rate except for the 0-24 age group which had a 11 percent increase.

Table 30 presents hospitalization rates for disabled and aged Medicare beneficiaries as well as ESRD persons to illustrate the morbidity of this population relative to other persons receiving Medicare benefits. Hospitalization figures from Table 29 are used so the comparison is essentially between dialysis patients and the aged and disabled Medicare beneficiaries. Dialysis ESRD patients are hospitalized four times as often as disabled beneficiaries and 4.6 times as often as aged beneficiaries. The length of stay per discharge for dialysis patients (10.7 days) is slightly higher than that of disabled beneficiaries (10.5 days) and slightly lower than that of aged beneficiaries (10.8 days). As a result, the days of care per 1,000 ESRD beneficiaries of 16,874 is 4.6 times as great as the aged days of care rate (3,672/1,000) and 4.1 times as great as the disabled days of care rate (4,123/1,000).

TABLE 27 Hospitalized Persons by Number of Hospitalizations
1980 and 1981

	1980		1981	
	Number of Persons	Percent of Persons	Number of Persons	Percent of Persons
All Persons	57,814	100%	64,059	100%
Not Hosp.	16,350	28%	19,235	100%
1 Hosp.	17,362	30%	18,953	30%
2 Hosp.	10,343	18%	11,256	18%
3 Hosp.	6,080	11%	6,539	10%
4 Hosp.	3,528	6%	3,688	6%
5 + Hosp.	4,151	7%	4,388	7%

SOURCE: ESRD MEDICAL INFORMATION SYSTEM
INPATIENT STAY RECORDS, 1980 AND 1981

TABLE 28 Hospitalization Rates for Medicare ESRD Beneficiaries by Age, Sex, and Race; 1980 and 1981 (Including Transplant Patients)

	1980				1981			
	ESRD Persons (July 1)	Discharges/ 1,000	Days of Care/1,000	Average Length of Stay	ESRD Persons (July 1)	Discharges/ 1,000	Days of Care/1,000	Average Length of Stay
Total	57,814	1,678	19,381	11.5	64,059	1,653	18,691	11.3
Age								
0-24	4,277	1,604	19,559	12.2	4,630	1,737	20,243	11.7
25-44	15,621	1,570	18,668	11.9	17,732	1,566	17,802	11.4
45-64	22,888	1,656	18,444	11.1	25,568	1,651	17,967	10.9
65+	15,028	1,846	21,498	11.6	16,109	1,728	20,368	11,8
Sex								
Male	31,804	1,608	18,628	11.6	35,168	1,587	17,822	11.2
Female	26,010	1,763	20,301	11.5	28,891	1,733	19,747	11.4
Race								
White	39,459	1,695	19,689	11.6	43,266	1,681	19,116	11.4
Black	15,028	1,679	19,194	11.4	16,927	1,634	18,360	11.2
Other/Unknown	3,331	1,470	16,550	11.3	3,870	1,422	15,363	10.8

SOURCE: ESRD MEDICAL INFORMATION SYSTEM
INPATIENT STAY RECORDS, 1980 AND 1981

TABLE 29 Hospitalization Rates for Medicare ESRD Beneficiaries by Age, Sex, and Race; 1980 and 1981 (Excluding Transplant Patients)

	1980				1981			
	ESRD Persons (July 1)	Discharges/ 1,000	Days of Care/1,000	Average Length of Stay	ESRD Persons (July 1)	Discharges/ 1,000	Days of Care/1.000	Average Length of Stay
Total	53,896	1,591	17,320	10.9	59,986	1,570	16,718	10.7
Age								
0-24	3,315	1,137	11,529	10.1	3,650	1,332	12,848	9.6
25-44	13,610	1,393	14,534	10.4	15,641	1,405	13,947	9.9
45-64	21,951	1,608	17,074	10.6	24,595	1,606	16,677	10.4
65+	15,020	1,845	21,480	11.6	16,100	1,727	20,351	11.8
Sex								
Male	29,352	1,503	16,203	10.8	32,620	1,487	15,490	10.4
Female	24,544	1,696	18,655	11.0	27,366	1,668	18,183	10.9
Race								
White	36,462	1,593	17,384	10.9	40,151	1,583	16,895	10.7
Black	14,350	1,630	17,775	10.9	16,222	1,588	17,081	10.7
Other/Unknown	3,088	1,376	14,424	10.5	3,617	1,335	13,395	10.0

SOURCE: ESRD MEDICAL INFORMATION SYSTEM
INPATIENT STAY RECORDS, 1980 AND 1981

TABLE 30

HOSPITALIZATION RATES FOR MEDICARE AGED, DISABLED AND ESRD BENEFICIARIES

Medicare Group	Discharges/ 1,000	Average Length of Stay	Days of Care/1,000
Aged 1/	340	10.8	3,672
Disabled 1/	392	10.5	4,123
ESRD 2/	1,572	10.7	16,874

1/ Aged and Disabled rates are for 1978.
2/ ESRD rates are for 1980.

SOURCE: ESRD MEDICAL INFORMATION SYSTEM
INPATIENT STAY RECORDS, 1980 AND 1981

F.

TABLE 31 RATIO OF PATIENTS TRAINED FOR HOME DIALYSIS AND DIALYSIS PATIENTS TRANSPLANTED TO AVERAGE NUMBER OF DIALYSIS PATIENTS

JANUARY 1979 - DECEMBER 1982

	1979	1980	1981	1982
Average Number of Dialysis Patients	40,929	48,879	55,644	62,344
Patients Completing Home Training	2,874	4,565	5,212	6,282
Ratio of Home Trained Patients To Average Number of Dialysis Patients	.070	.093	.094	.101
Dialysis Patients Receiving a Transplant	3451	4051	4268	4772
Ratio of Dialysis Patients Receiving a Transplant to Average Number of Dialysis Patients	.085	.083	.077	.077

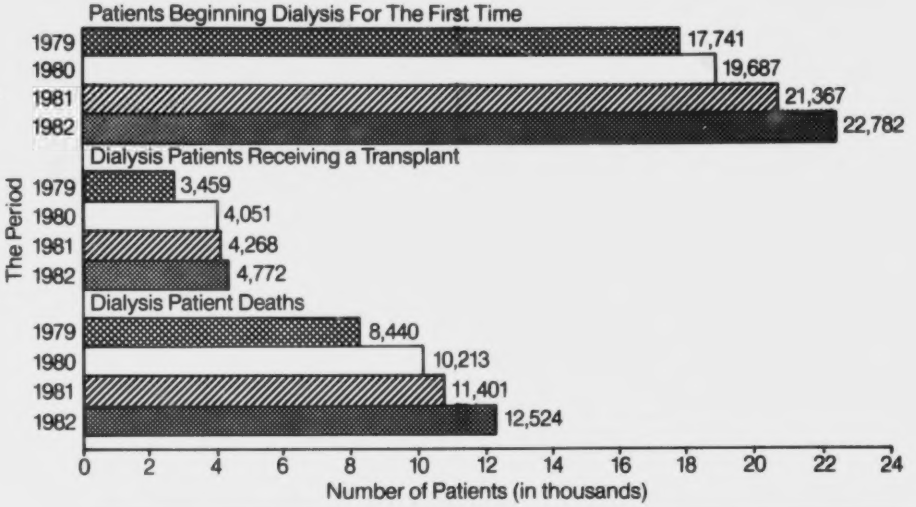
*There is an underrepresentation when compared to the number of transplants performed for the years because the survey captures data on the last known status of a patient as of the survey date.

SOURCE: ESRD MEDICAL INFORMATION SYSTEM
1979, 1980, 1981, AND 1982 FACILITY SURVEYS

G. Major Reasons for Changes in the Number of Patients Treated by Medicare Certified Suppliers of ESRD Services 1979 - 1982

Figure 18

Major Reasons for Changes in the Number of Patients Treated by Medicare Certified Suppliers of ESRD Services 1979-1982



SOURCE: ESRD Medical Information System 1979, 1980, 1981 and 1982 Facility Surveys

CHAPTER VII

MISCELLANEOUS

A. COST SAVINGS AND OTHER ESRD EXPERIMENTS

The Office of Research and Demonstrations within the Health Care Financing Administration (HCFA) is currently funding several studies related to the End-Stage Renal Disease (ESRD) program. Four of the studies described in this report correspond to specific mandates in Public Law 95-292. One of these Congressionally mandated studies was performed as an intramural study within the Office of Research, while the others are conducted under contracting arrangements with outside organizations. The remaining six studies are classified as Departmental/Agency initiatives. These projects address many of the basic policy, program evaluation, and cost containment issues involved in administering the ESRD program. Four of the Departmental initiatives are sponsored under HCFA's Discretionary Grants Program, while the other two are intramural staff studies.

A list of research and demonstration studies which are described in the following pages, and which are in various stages of completion, includes:

MANDATED STUDIES

1. A set of demonstration projects involving the reimbursement of home dialysis aides to encourage more patients to dialyze at home.

2. A study of the non-Medicare eligible ESRD patient population.

3. A study of the organizational effectiveness of the organ procurement agencies.

4. A study of physicians who care for ESRD patients--their practices, patients, and patient care.

HHS/HCFA INITIATED STUDIES

1. A study of the quality of life, quality of care, cost of care and rehabilitation of ESRD patients under different treatment modalities.

2. A study of costs, outcomes, and competition in the ESRD program.

3. A study of ESRD facility case-mix and the impact of patient severity on assignment to treatment modalities, utilization of services, and treatment costs.

4. A statistical modelling study of the ESRD delivery care system.

5. A statistical analysis of the ESRD administrative records pertaining to program entitlement, utilization of services, reimbursement, and patient survival statistics.

6. An epidemiological study of the relative risks of chronic low level exposure to solvents and heavy metals and the incidence of ESRD.

HOME DIALYSIS AIDE EXPERIMENTS

HCFA has sponsored three demonstrations which changed ESRD benefits by extending coverage to the services of a dialysis aide for maintenance dialysis sessions performed in the patient's home. The primary purpose was to test whether or not providing this extra benefit resulted in more patients choosing home dialysis as a treatment option. In addition, the impact on cost and quality of care was documented for analysis.

Two categories of paid aides were covered under the demonstrations. The first, known as "partners," were family or household members. The second, known as "assistants," were nonfamily or household members who could qualify to perform the patient aide service. A 3-year program was instituted whereby home patients and their aides could join the demonstration. Payment for services included training, transportation, and maintenance dialysis performance sessions. Partners and assistants received payment for the above services; however, partners received one-half the amount specified for assistants. Now that the 3-year demonstration period is completed, no new patients will be accepted into the demonstration. However, for those that have enrolled, the benefits will continue through mid-1987.

The three contractors which were chosen to design and implement these demonstration projects were System Sciences, Inc., Research Triangle Institute, and the University of Utah. The System Sciences demonstration began on April 1, 1978; it involves the participation of eight experimental facilities located in six different states: New York, Massachusetts, Mississippi, Florida, Minnesota and California. The Research Triangle Institute demonstration began on October 1, 1978; it involves the participation of 10 dialysis facilities located in North Carolina. The University of Utah demonstration began July 1, 1978; it involves the participation of eight experimental facilities located in Utah and Colorado. Prior to these demonstrations, there was a decreasing trend in the proportion of patients using home dialysis. Results thus far show increases at the experimental sites in the percentage of patients choosing the home environment. The Research Triangle experience reported that home patients increased by 45 percent in North Carolina and by 25 percent in Tennessee (the control state). In the System Sciences demonstration, 43 percent of the new patients in the demonstration facilities chose to use the home environment, whereas only 16 percent of the new patients in facilities not paying for home aides elected the home option for maintenance dialysis. In the Utah project, preliminary figures indicate an increase in the proportion of home users of 6 percent. Of all new patients in this demonstration, 41 percent chose the home environment compared to 29 percent in the control group.

The results of all three demonstration projects were independently evaluated by the Orkand Corporation under a separate contract awarded in September 1979. Orkand's evaluation focused on three main issues: (1) whether the availability of paid home dialysis aides increases the number of ESRD patients who choose to dialyze at home; (2) whether paid aides are cost effective to the Medicare program, and (3) whether paid home dialysis aides can be provided without adversely affecting the quality of care received by ESRD beneficiaries.

The evaluators summarized their findings in the final report as follows:

"SUMMARY OF KEY FINDINGS"

> The evaluation of the home aide reimbursement demonstrations resulted in several important findings about the effects of the home aide program on the cost of dialysis services, as well as findings regarding the characteristics of dialysis services and ESRD patients in home-based and facility-based dialysis settings. The key findings from the study are summarized below:
>
> - Based on the detailed analysis of 27 facilities, it was found that cost of dialysis in the home settings was less than two-thirds the maintenance dialysis cost in the facility setting when the experimental provision of aide payment was excluded from the calculation. When aide payments were included, the cost of the home setting was just over 70 percent of the cost of facility dialysis. The average cost per maintenance dialysis in the facility setting was \$150.79, and for home dialysis was \$93.59 without aide payments and \$107.50 with aide payments.
> - Training patients to dialyze at home is an expensive process. The average cost per home training dialysis was \$375.49. In order to offset the high training costs with the lower home dialysis costs relative to facility costs, it was found that 55 percent of the facilities had a payback period of less than 6 months, and two-thirds had a payback period of less than a year when the cost of payments to aides was excluded.
> - The cost of facility-based maintenance dialysis was found to be lower in the for-profit facilities (\$131.67) than in the not-for-profit facilities (\$157.48).
> - Similarly, the cost of home dialysis was lower in the for-profit facilities (\$87.54) than in the not-for-profit facilities (\$95.85).
> - The cost of home dialysis training was higher in the for-profit facilities (\$475.44) than in the not-for-profit facilities (\$333.62).
> - The proportion of home-based patients in the paid aide experimental group increased 4.6 percent while the proportion of home-based patients in the control group decreased by 1.5 percent during the first 21 months of the demonstration.
> - Overall, there appeared to be little or no differences between hospital-based and free-standing facilities in the demographic and medical characteristics of hemodialysis patients.
> - Home-based hemodialysis patients were found to be generally younger, in better physical condition, and to have higher personal and family income levels than facility-based patients.
> - Fewer home-based hemodialysis patients experienced changes in marital status (divorce and separation) than facility-based patients. Both patient groups experienced increases in unemployment rates after the initiation of dialysis treatments. Changes in marital and employment status were generally attributed by patients to be a result of renal disease and the requirements of dialysis.
> - There were no adverse patient quality of care findings when comparing home patients with paid aides to facility dialysis patients.

A STUDY OF THE NON-MEDICARE ELIGIBLE ESRD PATIENT POPULATION

HCFA, in cooperation with renal dialysis and transplant centers, conducted an intramural study of the patients with ESRD who were not covered by Medicare. The study focused on determining the number of nonentitled ESRD Patients and the burden of their treatment costs. Data on person counts and total dollars billed were collected on both center and home dialysis patients by primary source of support, which included the Veterans Administration (VA), Medicaid, State ESRD programs, Blue Cross and other private health insurance, and self-support. Information on the number of nonentitled transplant patients was also collected. The intent of this Congressionally mandated study was to estimate the cost to the Federal Government if Medicare coverage were extended to this population.

A report, based on the results of a facility survey questionnaire, has been prepared which contains descriptive data on: (1) the number and percentage of ESRD patients by treatment modality (dialysis or transplantation), treatment setting (home, hospital-based, or free-standing provider), entitlement status (awaiting entitlement or not awaiting entitlement), and by primary payment source; and (2) the distribution of ESRD facilities reporting bad debts from coverage limitations or experiencing excessive delays in reimbursements by payment source. In general, the study showed that a large proportion of dialysis patients who were ineligible for Medicare were already supported in part or totally by other Federal programs. Specifically, Medicaid and the VA are the primary payment sources for 67 percent of the patients who were unentitled and not awaiting entitlement. Thus, if a decision were made to extend Medicare coverage to all unentitled ESRD patients, regardless of payment source, much of the additional costs to Medicare would simply reflect a transfer of payments from one Federal source to another.

DEVELOP METHODS FOR INCREASING PUBLIC PARTICIPATION IN KIDNEY DONATION PROGRAMS

In October 1981, the University Health Policy Consortium began a multi-year study into the methodologies and structures of organ procurement. The first phase of this HCFA-sponsored grant was to study the operational efficiency of the Independent Organ Procurement Agencies (IOPAs) and to measure their effectiveness in obtaining and distributing kidneys. The second phase of this study was to extend the survey to the hospital-based organ procurement agencies. The importance of effective procurement of kidneys is essential to bring the current imbalance between consumer demand for transplants and the number of transplants actually done into equilibrium and to meet the Congressional intent to promote this treatment modality where medically appropriate.

In the first phase of this comparative study, the researchers surveyed all of the free-standing independent agencies. In the first paper, "Organizational Effectiveness in Organ Procurement: A Study of Independent Organ Procurement Agencies," the principal investigator reported on his findings that the IOPAs deserved their reputation as the most effective sector of the organ procurement system. On the average, the IOPAs procure kidneys from 14.4 percent of the potential donors at an average cost of $6,400 per organ. The average wastage rate among the IOPAs is 22.4 percent. The major determining factor in organizational success according to the researchers is the degree to which the agency can induce the medical professionals to refer potential donors to it. This marketing function is viewed as the core technology of organ procurement. A considerable variation in the success of individual IOPAs was observed in both the effectiveness of their procurement efforts (from 3 percent to 58 percent of potential donors) and their per kidney costs (from $3,000 to $12,000), and the results are largely correlated with the effectiveness of their professional marketing efforts. In a second paper, "Obtaining Replacements: The Organizational Framework of Organ Procurement," the author discusses the organ procurement system, its sources, organization, scale, and the nature of its "core technology" - i.e., the organizational tasks essential to its success. Excerpts from the author's conclusions follow:

> "This is a question for public policy because the End-Stage Renal Disease Program has made the Federal government the sole purchaser of human kidneys. It has financial implications for the ESRD Program as transplants can be less expensive than dialysis. It has human implications because a successful transplant is both medically and socially superior to dialysis. Quality of life is far better."
>
> "The experience of the Independent Organ Procurement Agencies demonstrates that it is possible to greatly increase the number of kidneys retrieved in the United States under present laws. What is needed is an acceptance of organ procurement as an exercise in public service marketing aimed, primarily, at medical professionals who can refer potential donors and, secondarily, at the families of those donors.
>
> "Improvements are urgently necessary. We cannot now meet the demand for transplants. If hopes for the new immunosuppressant drugs are even partially fulfilled, rejection rates can be expected to drop making transplants a yet more desirable treatment. In addition the organ procurement industry faces some very difficult problems arising from the increasing demand for organs other than kidneys. Eyes and skin have long been needed and in recent years livers also have been transplanted. How OPAs, now funded solely to procure kidneys, will deal with these new demands is unresolved. Certainly a strong and effective system will have a far greater probability of adapting to the increasingly complex organ transplantation world of tomorrow. All

> this argues for a serious commitment to organizational reform and development along the lines recommended in this article. Such changes involve minimal risks and possible immense gains. If these 'safe' changes can generate enough transplantable organs to meet the Nation's needs, then more radical policy changes will be unnecessary. Only if organizational reform fails ought we to consider removing 'altruism' from organ donation."

In a third paper, "Encouraging Altruism: Public Attitudes and the Marketing of Organ Donation," the author discusses the public's attitudes toward organ donation and considers what can and is being done to foster the willingness to donate. In this paper, a marketing framework is developed for organ donation which defines the "product" being sold as the act of donation and equates the "price" of the product to the variety of psychological costs associated with organ donation. The marketing strategy is then developed from the basis of considering the nature and benefits of the product being sold and the prices of this public service donation. The distribution of attitudes by the population or its market segmentation is also discussed.

The basic problems of procuring kidneys for transplantation are two-fold: first the procurement agency must obtain information about and access to potential donors. The necessary final stage of the process is to obtain permission from a responsible relative of the deceased for removal and transplantation of the organs. Although public opinion surveys have shown a positive attitude by the public toward organ donation, this is not the same as a willingness to take concrete action. Even in those instances where the individual signed a donor card, the hospital and organ procurement agency will not excise an organ without the express written permission of the deceased's family. Thus, the marketing strategy must identify and appeal to the motivations that influence families to permit donations such as:

> "...they may be acting out of altruism, they may be carrying out the deceased's wishes; they may be acting to mitigate the impact of the death; or, they may be taking an opportunity to 'rehabilitate' the deceased via a socially approved act."

The authors discuss the cost of involvement in organ donation as highly variable across individuals, and, generally, higher than one might have imagined. The primary cost of involvement is confronting fear. One not only must deal with one's own mortality, but also deal with the anxiety and perhaps anger that results. The researchers also noted that there are enough salient differences among population groups to make market segmentation worthwhile. In particular, age, race, and possible class differences are the most important subgroups of the population for targeting the market. Young persons (say under 15 years of age) and persons over 55 are excluded from the target audience. Black Americans are far less likely to express support for organ donation than whites and have far less donation rates. The reasons for this are complex and not fully known, but certainly the variation in the donation rates suggests the possibility of a diverse marketing strategy. The author concludes:

"In the end, all one ought to expect from public marketing in organ procurement is to increase the salience of the altruistic impulse. The death of a family member generally brings with it grief, love, guilt, and fear. This is not the best environment for the introduction of unselfish generosity to strangers. But if public marketing can increase people's emotional commitment to organ donation before tragedy strikes, a family can carry into the hospital altruism as well as dread. This would decrease the psychological distance that needs to be travelled to decide to authorize organ donation. Certainly nothing can decrease that distance so effectively as an explicit commitment to the deceased based on earlier discussions. But equally certainly, the underlying motivation of all who contribute to the decision to donate must be willingness to help strangers without the least prospect of personal advantage."

The second phase of the study involving the hospital-based procurement agencies was completed December 1983. The final phase of the study updated the IOPA analyses and integrated the HOPA and IOPA reports into a single, comprehensive analysis of the entire organ procurement system of the United States. A final report was submitted to HCFA in March 1984 which combined the organizational, financial and organ acquisition data gathered from the surveys of the IOPAs and HOPAs. The final report also contained recommendations on both operational matters in organ procurement and on possible ways in which HCFA could intervene in the procurement system, via regulations and/or reimbursement policies, to improve the yield of transplantable organs and contain program costs.

STUDY PHYSICIAN PRACTICES AND REIMBURSEMENT POLICIES FOR THE DELIVERY OF RENAL SERVICES

The results of three reimbursement studies by Northwestern University were described in the 1981 ESRD Annual Report to Congress. The present research in this important area builds upon this research base and should provide additional information in meeting the Congressional mandate to conduct a full and complete study of the reimbursement of physicians for services furnished to patients with ESRD.

One study, which is presently in progress, is being performed as an intramural effort by the Office of Research. The intramural study will examine the effects of the physician reimbursement methods on program costs and choice of treatment setting, controlling for individual patient characteristics. The study will also examine whether there are differences in treatment style (e.g., frequency of dialysis or frequency of physician contact) that can be associated with the different reimbursement methods. Statistical regression techniques will be used for the analyses.

The study involves the analysis of a unique data set on ESRD patients, their sociodemographic characteristics, the characteristics of their regular dialysis or backup facilities, and Medicare reimbursements on their behalf. The data set was constructed by merging program data with a survey file collected by the Research Triangle Institute for the "Home Dialysis Study" published in 1978. The data file contains information on 469 patients and 39 facilities, with respect to the first year of 1976. That earlier study examined the factors which led to the selection of home or facility as the treatment site for individual patients.

The data analyses were begun in the fall of 1981. The results of the study will be a research report and policy paper that will be completed by Spring 1984.

A second study was initiated in March 1982 with a grant to the Division of Research in Medical Education at the University of Southern California School of Medicine. In this project entitled, "Physicians Who Care for End-Stage Renal Disease Patients: A National Study of Their Practices, Patients and Patient Care," the researchers proposed to design and conduct a national physician-oriented study of the time and effort allocated to various professional activities and patient care services with the target population being those physicians who render care to patients with ESRD. The study is all-inclusive to the extent that the participating physicians are asked to report on their entire practice and the full array of their professional activities. The physician population was limited to those who were reimbursed under the alternative method and the sample was selected from those physicians who are linked administratively and operationally for some patient care with one or more dialysis facility -- making it possible to draw statistically valid conclusions about the actual care provided to both ESRD and non-ESRD patients, and with the ESRD patient services explicitly linked to a particular type of dialysis facility and dialysis modality.

Using a log diary approach, detailed information was obtained on specific services rendered to ESRD beneficiaries by 327 physicians. These data are currently being analyzed. The final study report will include both a descriptive analysis of the data, identifying patterns evident in the data by region, facility workload and case-mix as well as more rigorous statistical analyses to examine the complex interrelationships between patient characteristics, physician characteristics, facility characteristics, and variations in treatment. The final report should be available in Spring 1984.

A STUDY OF ALTERNATIVE TYPES OF THERAPY FOR ESRD PATIENTS

HCFA awarded a grant, "The Impact of Alternative Types of Therapy on Patients with End-Stage Renal Disease," to Battelle Memorial Institute's Human Affairs Research Center in January 1981. The study focuses on several variables of interest to the program including an examination of quality of life, quality of care, and cost of care to patients undergoing different types of therapy for treatment of ESRD. The study also examines the extent of disability among dialysis patients and assesses the potential for improving the lives of dialysis patients by changes in the types of therapy or through the provision of rehabilitation services. Four treatment modalities are included in the study: facility dialysis, home dialysis, continuous ambulatory peritoneal dialysis (CAPD) and renal transplantation.

During the first year of the study, the researchers developed a detailed study protocol and obtained participating agreements and institutional review board clearances. A two-stage sampling design based on a stratified probability sample of ESRD patients by treatment modality from 11 facilities and transplant centers was developed and a study universe of 950 renal patients was drawn. Several different survey instruments were developed and pretested. The primary data collection instrument, the patient interview schedule, was administered to the study population. Other instruments included a patient health, medical care, and treatment expenses diary, and a chronic renal disease patient medical records data abstraction form.

During the second year of the study, the major activities included the completion of the data collection activities, the preparation of the data tapes, the initial data runs, including descriptive, univariate and selected cross tabulations, simple chi-square tests of differences, analysis of variance and covariance, multiple regression analyses, and the publication of 13 supporting documents and seven major papers. For analytical purposes, the data are grouped into nine data clusters corresponding to the following types of variables: sociodemographics, health status, functional impairment, work disability, type of therapy, social environment, quality of care, and cost of care. Several standard measurements and indexes were utilized in the study to permit cross-validation with other research studies.

The major papers which have been published and their abstracts are as follows:

(1) Case-Mix, Treatment Modalities, and Patient Outcomes: Results of the National Kidney Dialysis and Kidney Transplantation Study.

> "Many studies which have examined the outcomes of patients with end-stage renal disease have attributed differences in observed outcomes to treatment modality. It is unclear, however, whether these differences are truly due to treatment modality or whether they are a result of initial patient selection differences, more appropriately described as case-mix differences. In this paper data are analyzed for 859 patients from 11 different dialysis and transplantation centers who are on four different treatment modalities -- home hemodialysis, in-center hemodialysis, continuous ambulatory peritoneal dialysis, and transplantation. It is found that substantial case-mix differences exist among patients on these four major treatment modalities. With regard to outcomes it is found that patients on kidney transplantation and home hemodialysis are more likely to be working and have a lower level of functional impairment than patients on the other modalities. The analyses also show that while case-mix can be an important determinant of outcomes, a modality effect persisted once sociodemograhic and medical case-mix factors were statistically controlled. Finally, a direct comparison of patients

across centers suggests that, in addition to a case-mix and a modality effect, there appears to be a unique center effect which accounts for differences in patient outcomes. Based on results presented here, it is suggested that future studies which relate treatment modalities to patient outcomes must take into consideration the fact that any relationship between the two may be the result of one or more of the following effects--case-mix, modality, or center."

(2) A Comparative Assessment of the Quality of Life of Patients Undergoing Treatment for Chronic Renal Failure.

"The quality of life of 859 patients from 11 dialysis and transplantation centers across the United States was assessed. All patients were on one of four treatment modalities--home hemodialysis, in-center hemodialysis, continuous ambulatory peritoneal dialysis, and transplantation. The results show that the relationship between treatment modality and 17 subjective indicators of quality of life (i.e., life satisfaction, general well-being, and happiness) remain relatively unchanged once patient case-mix factors have been controlled. Case-mix factors subjected to analyses include age, sex, race, education, and comorbidity. These results suggest that once patient case-mix has been controlled, treatment modality still independently affects patients' assessment of quality of life. Based on these results it is possible to rank treatment modalities according to the quality of life associated with them. Transplant patients consistently report a higher quality of life than patients on other treatment modalities, although home hemodialysis patients are similar in many respects. CAPD patients appear to have a higher quality of life than failed transplant patients, while in-center hemodialysis patients are clearly the worst off. Finally, quality of life comparisons between ESRD patients and the general population reveal that the life circumstances of ESRD patients are not as poor as previously envisioned."

(3) Functional Impairment, Work Disability, and the Availability and Use of Rehabilitation Services by Patients with Chronic Renal Failure.

"Recently, there has been an increased awareness of and concern about the rehabilitation of patients with end-stage renal disease (ESRD). Little is currently known about the work disability, functional impairment, and use of rehabilitation services by ESRD patients. In this paper data are analyzed for 859 patients, from 11 dialysis and transplantation centers who are on four different treatment modalities--home hemodialysis, in-center hemodialysis, continuous ambulatory peritoneal dialysis, and transplantation. Results presented here reveal that transplant patients experience the least functional impairment, followed by home hemodialysis patients, failed transplant patients, in-center hemodialysis patients, and CAPD patients. Ignoring distinctions among patients on different treatment modalities, approximately 32.0 percent of the patients in this study were unable to carry on normal activity. The remainder of the patients were either unimpaired or only minimally impaired. Work disability among patients also varied according to treatment modality with transplant patients most likely to be working. Overall, 30.0 percent of the patients were working either full-time or part-time. Approximately 39.0 percent of the patients said they were disabled. Finally, only 54.6 percent of the patients made use of available rehabilitation services.

Transplant patients, both those with failed and functioning grafts, used more rehabilitation services than the other patient groups. Based on these results, it would appear that a larger number of patients could potentially benefit from the use of rehabilitation services. For unspecified reasons patients are unaware of services which are available to them, choose not to use the services, or are denied access to the available services."

(4) Labor Force Participation Among ESRD Patients.

"Recently, there has been an increased concern about the rehabilitation of patients with end-stage renal disease (ESRD). In particular, interest has focused on their participation in the labor force. In this paper results are presented based on the analysis of data obtained from 859 patients associated with 11 dialysis and transplantation centers in the U.S. The patients are on four different treatment modalities including home hemodialysis, in-center hemodialysis, continuous ambulatory peritoneal dialysis (CAPD), and transplantation. When unadjusted for patient case-mix, the data show significant differences in the labor force participation among patients on all four treatment modalities. More specifically, transplant patients are more likely to be working followed by patients on home hemodialysis, in-center hemodialysis, and CAPD. Once patient case-mix (i.e., age, gender, race, education, wealth, and health) is statistically controlled, however, several of these differences are greatly reduced. It is noteworthy that despite case-mix differences, transplant patients continue to have the greatest likelihood of participating in the labor force and that CAPD patients are the least likely. Home hemodialysis patients, when compared with patients on all other treatment modalities, are only slightly more likely to be working than their in-center counterparts. A more detailed multivariate analysis, however, reveals that white, male, home hemodialysis patients between the ages of 25 and 59 are significantly more likely to be working than in-center patients of these characteristics. This finding does not hold, however, for either white females, nonwhite females, or nonwhite males in this age range. It is concluded that these findings have important implications for public policy but must be carefully evaluated in light of acknowledged limitations in both the data and the analyses."

(5) Health Services Utilization and Disability Days: Indicators of the Quality of Patient Care Among ESRD Patients.

"This report focuses on several outcome measures as indicators of the quality of care of end-stage renal disease (ESRD) patients. Variables reflecting hospital utilization, disability days and physician visits were compared for five different treatment modality groups. With respect to hospital utilization, statistically significant differences were observed across treatment modalities. In addition, a relationship was observed between the utilization of hospital services and length of time on current treatment modality. Statistically significant differences in hospital utilization were observed across treatment modalities among patients who had been on their current treatment modality for one year or less. However, among patients who had been on their current treatment modality for more than one year, statistically significant differences across treatment modalities were not observed.

Differences in outcome variables were then examined, controlling for the sociodemographic (age, sex, race, education) and medical characteristics (diabetes, comorbidity, length of time on current modality) of the patient groups. Medical factors, in particular comorbidity and length of time on modality, were more important than the sociodemographic factors in explaining the observed variation in health services utilization across modalities. Treatment modality, however, remained a significant variable in the case of five of the seven utilization variables."

(6) Premorbid and Post-Treatment Functional Limitations Among Patients with Chronic Renal Failure.

"We report on the functional limitations of patients undergoing treatment for end-stage renal disease (ESRD). Results presented here clearly show that ESRD patients are more impaired at the present time than they were prior to the onset of kidney disease. Overall, patients in this study did not differ, regardless of their current treatment modality, in their level of functional impairment prior to the onset of kidney disease. But, at the present time significant differences across patients on different treatment modalities are found. Both transplant and home hemodialysis patients are found to be less debilitated than in-center hemodialysis patients, CAPD patients, and patients who have experienced a failed kidney transplant. Indices of both general and specific functional impairment are consistent in this regard. Several explanations are offered for the association between treatment modality and functional impairment, including the possibility that patient case-mix may account for the observed differences. The study results also suggest that patients could potentially benefit from more aggressive physical rehabilitation efforts. Only 16 percent of the patients in the study had ever made use of physical therapy. Finally, the need for a longitudinal study of ESRD patients is indicated."

The final year of the study will be devoted to the multivariate analysis of the data and the preparation of several additional papers. The topics will address each type of therapy, individually, and comparatively, in greater detail. All of of the major issues of the program, including cost, quality of care, quality of life, rehabilitation and patient assignment to types of treatment modality will be addressed. The final study results are expected by June 1984.

COST OUTCOMES AND COMPETITION IN THE ESRD PROGRAM

In June 1981, HCFA awarded a 2-year grant to the Urban Institute to examine the variations in costs and treatment outcomes to identify those factors associated with lower cost and/or higher survival rates.

Factors to be considered include case-mix, facility size, and physician compensation methods. In addition, a specific focus of the project will be an examination of the effects of competition between ESRD facilities. The project will assess whether free entry into the dialysis market either reduces costs or provides increased benefits to patients. A survey will be conducted to identify facility initiatives to attract and retain patients where several facilities are available to beneficiaries. Finally, the study will also examine the cost impacts of the certificate-of-need and minimum utilization rate requirements.

The study is primarily based on an analysis of the ESRD MIS data base (facility survey, cost survey, nonreimbursement patient records and billing records) and supplemented by a telephone survey of 700 facility medical directors (300 independent and 400 hospital-based facilities).

The most important policy areas to be covered in the study are:

(a) Provider Reimbursement

- Should facility and/or physician reimbursement be based on capitated payment per patient with such payment covering all costs including hospital charges?
- Should case mix adjustment be an element of reimbursement?
- What elements of costs are directly related to facility size and how should reimbursement be designed to encourage optimal size?
- Does ownership and facility type affect total cost in ways not attributable to case mix?

(b) Physician Compensation

- What is the relationship between physician compensation method and total cost per patient?
- Does the present physician capitation method need modification to provide better cost-saving incentives?
- Are there different health outcomes under the two methods?
- Should one method be emphasized over the other?

(c) Competitive Effects

- Does restriction of the number of stations through minimum utilization rates and certificate of need actually help to control costs?
- Would free entry into the dialysis market either reduce costs or provide increased benefits to patients?

(d) Ownership Status

- Are there measurable differences in the health outcomes of patients treated at for-profit facilities?
- Should entry by investor-owned firms be encouraged or discouraged?

(e) Self-Care Patients

What are the savings in self-care when case mix adjustments have been included in the analysis? Do these savings warrant continued emphasis on self-care?

(f) Home Dialysis

- What contributions to a center's operating costs are made by home patients?
- When total costs, including all hospital care are considered, how much savings result from home care?

Two reports have been published to date and four additional ones are anticipated during the course of the study. In the first report: "Pro-Competitive Health Insurance Proposals and Their Implications for Medicare's End-Stage Renal Disease Program," June 1982, the authors discuss several ways of inducing competitive behavior into the ESRD program, although significant implementation problems would exist that would require careful attention to both cost and quality-access incentives.

In the second report: "Competition and Efficiency in the End-Stage Renal Disease Program," December 1982, the authors argue that although analyses of costs and productivity are useful, they are not conclusive in determining reimbursement levels. The problem is that reimbursement levels and competition among providers determine the level of amenities offered and these in turn influence the costs rather than the converse. The thesis is thus that the determination of the reimbursement level requires a prior political decision on the level of amenities such as conveniences, access, and medical quality the taxpayers will finance.

The focus of the report is on the impact of the presence or absence of competition. A simple model is presented to show that the level of amenity can be affected by the level of reimbursement and the level of competition. Then the argument is developed that this amenity bias can affect estimates of costs, cost functions, and production functions. Next the authors present empirical evidence to show that this is more than theoretical speculation. With output price approximately fixed, they found that profits from dialysis services are indeed affected by the degree of competition. Competition is also shown to be positively related to an observable measure of the level of amenity. Finally, the implications of this competition-amenity interaction on estimating and interpreting a production function for this type of health care are illustrated. The authors indicate that such estimates are subject to a previously unrecognized "unobserved amenity bias."

Four additional reports covering (1) Total Program Costs/Patients (May 1983); (2) Analyses of Response Rates to Dialysis Medical History Form (June 1983); (3) Evaluation of Differences in Dialysis Rates Per Capitation (August 1983); and (4) Outcomes in ESRD Program Death Rates (November 1983) will be forthcoming.

THE IMPACT OF CASE-MIX AND FACILITY CHARACTERISTICS ON TREATMENT COSTS AND UTILIZATION OF SERVICES

The primary focus of this multi-year study by the University Health Policy Consortium is on the development of a case-mix model ESRD patients and its application in studying the relationship between case-mix, assignment of patients to treatment modalities, and treatment costs.

The study is based on an analysis of 10 years of patient-oriented, longitudinal data from the Michigan Kidney Registry. The data for the 4,400 Michigan patients in the study will be supplemented with information from the ESRD program files. For a small subset of patients (250 patients), a detailed collection of changes in the patient's co-morbidity will be obtained from medical record abstracts.

In general, the study design employs a clustering approach to understanding the characteristics of patients which influence the intensity of service utilization. The resulting patient risk groups will be analyzed with regard to the following dependent variables: (1) length of survival; (2) movement within the system to different modalities and settings; (3) organizational characteristics of providers from whom the patients receive care; and (4) subsequent comorbidity.

In 1982 three papers on the progress of the study were submitted to HCFA. In the first paper, "An Overview of Case-Mix and Reimbursement," the authors present the results of an exploratory study of the relationship between health characteristics, modality choice, morbidity and survival in ESRD. This study was a precursor to the main study and it involved a retrospective analyses of the experience of 225 patients from a large New England teaching hospital. In this study, the patient's treatment modality appeared to represent a prognostic stratification by the clinician which incorporated a subjective assessment of risk and resulted in patients with the highest risk group being assigned to in-center dialysis while patients in the lowest risk group were assigned to transplantation. Thus, the initial patient profile - i.e., the characteristics associated with age, race, etiology of the disease, and the prevalence of comorbid conditions strongly influenced survival dynamics by impacting on both the allocation of patients to treatment modalities and on the differential outcomes of the treatment.

In the second paper, "Initial Patient Characteristics and Risk in End-Stage Renal Disease: The Development of Severity Groupings Through a Survival Analysis," the authors continued their ESRD studies by examining the stability of the patient characteristics in defining levels of severity of patients' illnesses and in investigating whether the different facility types accept differing severity distributions of patients. For this study, the researchers used longitudinal data from the Michigan Kidney Registry and analyzed the experience of 4,400 patients.

The initial diagnostic groupings were formed by using expert clinical judgment and then further reduced, analytically, to small statistically homogeneous groups. The resultant clusters incorporated a mixture of primary diagnosis and/or comorbid conditions. The authors summarized this phase of their work as follows:

> "An approach to the analysis of patient severity in ESRD has been presented. Characteristics of patients have been indentified which are related to longer or shorter survival times (duration of treatment). Through the use of two models of survival analysis, a proportional hazard model and logistic regression, we have presented an alternative framework to understanding patient severity both in terms of overall survival during the course of treatment (proportional hazard) and one year survival from the start of treatment (logistic).

> Each model allows the definition of 5 risk groups which cluster patients of similar severity status together. Risk is defined as having three factors, age, comorbidity, and race which together predict survival. Our findings are consistent with clinical understanding of the pathways of ESRD. Further, we have for the first time, developed an approach which allows the analysis of case-mix in an ESRD facility. The 5 risk clusters in our model define distinct patient groups in terms of expected survival. That these groups would also differ in terms of utilization patterns and costs is a reasonable assumption, and one that will be tested at a later stage in our research."

In the third paper, "Patient Placement in ESRD Facilities: Case-Mix Differences Between Facility Types," the authors continue their analysis of case-mix as it relates to reimbursement policy. This paper presents the first part of an analysis of facility case-mix based on facility placement. In particular, the distribution of severity groups across facility types is examined. The authors conclude this phase of their analysis with the following discussion:

> "When patients are assigned to severity groups according to short-term risk, significant case-mix differences are found between hospitals and free-standing facilities as a group; the former being more severe. In addition, the case-mix in both hospitals and non-profit free-standing facilities is significantly more severe than in for-profit free-standing facilities.
>
> "When a patient's risk is considered over a longer period of time (over the course of treatment up to 10 years), there is not the strong relationship between severity group and facility placement when hospitals are compared to free-standing facilities. Even with a "long-term" definition of risk, however, for-profit free-standing facilities have a significantly less severe case-mix than either nonprofit free-standing or hospital-based facilities.
>
> "Overall, the largest case-mix differences are seen between for-profit and nonprofit facilities, both hospital-based and free-standing. Hospitals do differ from free-standing facilities as a group, but the difference is not as strong as when they are compared to for-profit free-standing facilities alone."

In the next phase of the study the focus will be on patient transfer patterns between facilities by severity groups. Also, an examination will be made of the occurence of comorbidity after the initiation of treatment and the resultant facility response as it relates to transfer and hospitalization patterns.

STATISTICAL MODELLING STUDY OF THE ESRD DELIVERY SYSTEM

Indiana University was awarded a 3 year grant in 1979 to model the ESRD patient care system. In this statistical modelling study, the researchers were given program generated data to estimate the model parameters. Once the model has been established and tested it will be used to perform simulations of what impact changes in the incidence of the disease, type of therapy employed, or variations in entitlement provisions would likely have upon total program costs.

The analysis will address the following six specific sub-study areas:

1. Re-examine the cost-effectiveness of alternative therapies for ESRD
    - Revision of simulation model with updated cost and mortality data
    - Sensitivity of simulation of data and results

2. Impact of changes in patient selection
    - Alternative payments for home dialysis aides
    - Age and comorbidity factors

3. Rehabilitation features of treatment alternatives
    - Quality of life factors
    - Sensitivity of cost-effectiveness to quality of life factors

4. Reimbursement issues in ESRD
    - Documentation of reimbursement methods, including target rate and incentive reimbursement approaches
    - Cost-effectiveness equations as a function of payment method and dialysis mode.

The final report for this study was completed in June 1983.

INTRAMURAL ANALYSIS OF ESRD PROGRAM DATA

The ESRD program data is being analyzed through a series of intramural studies within the Office of Research. Then, depending upon the scope and purpose of each study, they will be released as research reports, published journal articles, internal memoranda, or used in presentations or talks. Over the past few years a number of separate "studies" have been completed. These include: "Life Expectancy and Use of Services by Persons With End-Stage Renal Disease Enrolled in Medicare," "Analyses of Indicators of Case-Mix Differences Between Free-standing Facility and Hospital Based Medicare ESRD Patients," "Trends in Incidence, Prevalence, Survival and Reimbursement in Medicare ESRD Patients," "Medicare Program Experience With End-Stage Renal Disease," "Uses of the End-Stage Renal Disease Medical Information System for Epidemiological Research," and "The Medicare Experience With End-Stage Renal Disease: Trends in Incidence, Prevalence and Survival." In the last study, which was published in the March 1984 HCFA Review, the overall trends in the Medicare ESRD Program are examined. Changes in incidence, prevalence, and patient survival are explored. In addition, changes in patient characteristics such as age, sex, race, and diagnosis are documented.

AN EPIDEMIOLOGICAL CASE-CONTROL STUDY TO DETERMINE THE RELATIVE RISKS OF CHRONIC LOW LEVEL EXPOSURE TO SOLVENTS AND HEAVY METALS AND THE INCIDENCE OF END-STAGE RENAL DISEASE.

HCFA is collaborating with the NIOSH in a case-control study to investigate if long-term exposure to industrial solvents, silica and heavy metals might be associated with the incidence of ESRD. Heavy exposures to many of these industrial products are known to increase the probability of kidney disease, but the effects of low level exposures are not known.

In this study, approximately 400 cases and an equal number of controls will be interviewed and questioned on the type and extent of exposure to these expected risk factors. The study is a community based study of males between the ages of 19 and 50 who live in the Detroit SMSA area and who have worked in the industrial plants.

The study is scheduled to begin in the summer of 1983 and will conclude by December 1985.

B. RESULTS OF BASIC KIDNEY DISEASE RESEARCH

A. General Description

The National Institutes of Health/National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases supports research within a broad area related to chronic renal disease. There are three main subdivisions of the Chronic Renal Disease Program: pathophysiology of chronic renal failure, renal transplantation, and maintenance therapies for end-stage renal disease.

Principal Research Areas of the Chronic Renal Disease Program

1. Pathophysiology of Chronic Renal Failure.

   These projects are devoted to the investigation of systemic abnormalities of uremia such as bone disease, anemia, and neurological, metabolic, gastrointestinal, cardiovascular, and endocrine problems. This area also includes studies of the biochemistry of uremia, nutritional/metabolic studies, and uremic toxicity. Investigations are directed to determine the causes of the abnormalities, underlying mechanisms of disease, and potential therapeutic procedures for treating or preventing such complications.

2. Renal Transplantation.

   These research projects are devoted to improving the methodology of renal transplantation and reducing the complications of patients subjected to this therapy. Studies cover such technical areas as organ preservation, immunosuppressive therapies, medical/surgical complications of transplantation, and applied transplant immunology specific to the renal area. Through better tissue matching, organ preservation, and improved technology of immunosuppression, increased functional graft and patient survivals are made possible. Another goal of research is to reduce complications of the transplanted patients.

3. Maintenance Therapies for End-Stage Renal Disease Patients.

   Studies in this area are directed toward improving the effectiveness of chronic renal diseases, maintenance therapies in terms of preserving residual renal function, as well as minimizing complications inherent to the therapeutic interventions as well as to the progressive renal insufficiency itself. Projects range over a broad area of applied research in maintenance, dietary interventions, hemodialysis, peritoneal dialysis, hemofiltration, complications of maintenance therapies, and development of refinement of methodologies. Selected epidemiological studies are also devoted to the evaluation of maintenance therapies by collection of clinical and basic demographic data and other relevant information.

B. Research Advances

The main techniques used as maintenance therapeutic modalities for chronic renal failure for more than 20 years have been dialysis and transplantation; both "half-way-technologies" are the only palliative treatment modalities which have become accepted methods of therapy. In 1981 dialysis was provided for over

68,000 patients and transplantation for 4800 patients in the United States during the same period of time.

I. KIDNEY TRANSPLANTATION

Transplantation is an effective means of treatment for patients with ESRD when well-matched related donor kidneys are available. Transplantation is less effective when cadaver kidneys are used. The necessity for long-term immunosuppressive therapy to minimize potential renal graft rejection and the high incidence of graft failure are responsible for lesser success of kidney transplantation as compared to dialysis as treatments for ESRD.

Adjuvant methods to increase graft survival by interventions such as splenectomy, non-specific blood transfusions, antilymphocyte globulin and treatment with Cyclosporin A (or cyclosporine), are being evaluated by several groups of investigators at present. Research advances in these areas are presented next.

1. BENEFICIAL EFFECT OF SPLENECTOMY IN GRAFT SURVIVAL OF CADAVER KIDNEY RECIPIENTS

Retrospective analyses of the value of splenectomy (surgical removal of the spleen) of some transplant groups have shown a benefical effect in some cases and no difference in others. It has been suggested that splenectomy minimizes the leukopenic (diminished number of white cells) effect of the immunosuppressive regimens necessary for renal graft survival. Since splenectomy is considered a major operation with potential complications, a prospective randomized clinical trial to compare the benefits of splenectomy vs. non-splenectomy in transplant patients was conducted under Institute's support.

Over a two year period, 299 renal allograft* patients receiving the same immunosuppressive treatment were randomized into the two groups: splenectomized and non-splenectomized recipients and then stratified according to transplant donor type. Graft survival at two years was 28% better in the splenectomized recipients of cadaver kidneys than in the non-splenectomized patients.

It is concluded that under the standard immunosuppressive regimen, splenectomy should be done in recipients of kidneys from either cadaver donors or from HLA non-identical selected donors.

Reference:

1. Najarian, J.S.: 5 PO1 AM 13038-14, University of Minnesota, Minneapolis, "Studies of Organ Transplantation in Animals and Man."

*allograft - organ transplanted from a genetically non-identical donor of the same species.

2A. EFFICACY OF ANTILYMPHOCYTE GLOBULIN AS AN ADJUNCT IMMUNOSUPPRESSIVE AGENT IN EARLY REJECTION EPISODES

Another adjuvant method to improve early transplant function and reverse acute rejection episodes is the use of antilymphocyte globulin (ALG) or antithymocyte globulin (ATG).

When particular fractions of animal serum made immune to human lymphocytes (white blood cells) or thymocytes (cells of the organ called thymus), called globulins, are injected into a transplant recipient, a marked suppression of cellular immunity results (1).

The clinical effectiveness of ALG or ATG, shown to be invariably superior experimentally in prolonging allograft survival to Azathioprine and Prednisone, has been difficult to establish (2). Some of the reasons for this difficulty are the frequent variability in the potency of batches of ATG or ALG, differences in the dosage-schedules followed by different groups of investigators, and insufficient number of patients to evaluate (2-4).

One of the larger recent clinical series has been reported by Cosimi and collaborators (5) who studied 104 cadaveric kidney transplant recipients given ATG in conjunction with Imuran and Prednisone (60 patients) or Imuran + Prednisone alone (44 patients). Significantly fewer early rejection episodes plus a definite decrease in overall steriod requirement were observed in ATG treated groups without increase in the incidence of infections. Functional graft survival was 10-13% higher in the ATG treated group at all time intervals.

Another study, the Kidney Transplant Histocompatibility Study (KTHS) (6) enrolled over 1500 cadaver transplant patients in a collaborative trial. Again, at all intervals studied up to 3 to 36 months post-transplant, allograft survival in patients given ALG treatment was 10-11% better than in those who had not received ALG.

In another randomized double blind study, including 64 patients receiving either ALG or the standard anti-rejection regimen (7), the effectiveness of ALG for reversal of established first rejection in recipients of first renal allografts was established. Graft survival was better with ALG (82%) than with standard regimen (61%); second rejection episodes were fewer in the ALG treated group.

Past and recent studies using ALG as an adjunctive immunosuppressive agent in primary cadaveric kidney transplantation show that treatment with ALG results in 10-15% improvement in functional graft survival for 1-2 years, with probably no alteration in patient survival. The incidence, severity, and ease of reversibility of early rejection reactions are improved with adjunctive ALG treatment and reduced steroid requirement in early rejection episodes both in living-related and in cadaveric kidney transplant patients.

The therapeutic levels of immunosuppression required and accompanying immunosuppressive regimens are yet to be clearly delineated under uniform and tightly controlled clinical research protocols.

2B. REVERSAL OF REJECTION EPISODES WITH MONOCLONAL ANTITHYMOCYTE GLOBULIN

Research studies with monoclonal antithymocyte gloubin (ATG), -- specific antibodies prepared following the complex technique of Kohler and Milstein--are still very preliminary. Nevertheless, Cosimi et al (5) reported the first clinical trials with monoclonal antibodies in the treatment of acute rejection of cadaveric transplanted kidney patients. In all cases, established rejection episodes were reversed within 2-7 days without addition of any therapy other than the monoclonal ATG and despite continued lowering of steroid dosages. During the subsequent 3-13 months follow-up, further rejection episodes occurred in 5 of the 8 patients; 6 of the original 8 renal allografts continued with excellent function (8).

Studies should continue in this promising research area.

References:

1. Strom, T.B., The Improving Utility of Renal Transplantation in the Management of End Stage Renal Disease. Am. J. of Med. 73:105, 1982.

2. Monaco, AP: Antilymphocyte Globulin: A Clinical Transplantation Research Opportunity. Am. J. of Kidney Dis. 2:67, 1982.

3. Rubin, R.H., Cosimi, A.B., et al: Effects of Antithymocyte Globulin on Cytomegalovirus Infection in Renal Transplant Recipients. Transplantation 31:143, 1981.

4. Kreis, H., Mansouri, R, et al: Antithymocyte Globulin in Cadaver Kidney Transplantation: A Randomized Trial Based on T-Cell Monitoring. K. Int. 19:438, 1981.

5. Cosimi, AB: The Clinical Value of Antilymphocyte Antibodies. Transpl. Proc. 13:462, 1981.

6. Barnes, B.A., Olivier, D: Analysis of NIAID Kidney Transplant Histocompatibility Study (KTHS): Factors Associated with Transplant Outcomes. I. Trans. Proc. 13:65, 1981.

7. Najarian, J.S.: 5 PO1 AM 13038-14, University of Minnesota, Minneapolis, "Studies of Organ Transplantation in Animals and Man."

8. Kung, PC, Tlla, MA et al: Strategies for Generating Monoclonal Antibodies Defining Human T Lymphocyte Differentiation Antigens. Trnasp. Proc. 12 (Suppl I) 141:12, 1980.

3. IMPROVED GRAFT SURVIVAL AND DECREASED INFECTIOUS COMPLICATIONS IN EARLY USE OF CYCLOSPORIN A

A new immunosuppressive agent (obtained from two species of fungi) shown to increase graft survival and decrease infectious complications in experimental animal models is now undergoing clinical evaluation.

A prospective randomized controlled clinical trial is underway (1) comparing Cyclosporin A (combined with low dose steroids (Prednisone)) with the conventional immunosuppressive regimen (Azathioprine + Prednisone) for the duration of graft function + antilymphocyte globulin (in the immediate post-transplant period) to adequately define the assets and liabilities of this new immunosuppressive agent and to put it in proper perspective for use in clinical transplantation.

Early evidence in this trial, which now includes approximately 120 patients, shows improved graft function, fewer rejection episodes, fewer infectious complications, and fewer hospitalization days in Cyclosporin A treated patients.

If the current trend continues, Cyclosporin A could provide an additional immunosuppressive approach to renal transplantation that could eventually be applicable in a large number of transplant centers and, therefore, increase the overall success of renal transplantation by prolonging graft survival, decreasing infectious complications in specific cases, and decreasing costs by decreasing hospitalization days.

Further evaluation and refinement in its prescription and usage are still required. Nephrotoxicity and hepatotoxicity appear to be dose-dependent and may be minimized by the use of a Cyclosporin A radio-immunoassay to guide drug doses (2). Doses of Cyclosporin A need close monitoring for serum levels and toxicity in each individual case.

Reference:

1. Najarian, J.S.: 5 PO1 AM 13038-14, University of Minnesota, Minneapolis, "Studies of Organ Transplantation in Animals and Man."

2. Keown, PA Stiller, CR et al: Immunological and Pharomacological Monitoring in the Clinical Use of Cyclosporin A. Lancet 1:686: 1981.

4. PRETRANSPLANT BLOOD TRANSFUSIONS HAVE INCREASED THE SUCCESS RATE OF CADAVER AND LIVING DONOR TRANSPLANTS

Drs. Opelz and Terasaki first noted that during the late 1960's, renal transplant candidates were freely transfused and the one year success rate for cadaveric grafts was about 60%. As the tendency to withhold blood transfusions to dialysis patients awaiting transplantation, to avoid apparent transfusion induced sensitization, became common practice, the graft success rate fell to about 45% (1).

In a series of 538 transplant patients, Dr. Terasaki et al (2) showed that three year graft survival in patients pre-transfused with one or more units of all blood products is 50% or higher compared to 30% for the non-transfused recipients. These investigators showed that one year graft survival is in the range of 60-70% for recipients receiving more than 10 pre-transplant transfusions compared to 35-45% for those receiving none (3). The benefits increase with the number of pretransfusions and is greater for the more mismatched grafts.

Investigations are underway to assess the role of sharing major or minor histocompatibility complexes* between blood donor and organ donor as necessary variables to achieve benefical effects of blood transfusions. Preliminary data indicate that mechanisms other than immunological enhancement may be responsible for the improved allograft survival accompanying pre-transplant blood transfusion (4).

Although the effect of blood transfusion on engraftment is well appreciated, somewhat more routine details, such as the number of units of blood needed for optimal graft survival, as well as the unresolved question of fresh vs. frozen vs. washed cells and precise methods of storage, remain controversial and should be further clarified. Further understanding of the mechanisms of the transfusion effect will provide clinicians with knowledge of the phenomenon so that transfusion protocols for dialysis patients awaiting transplantation will be more accurately developed.

Improvement of graft survival could not only mean improved quality of life for successfully transplanted ESRD patients, but could lead to appreciable cost savings for the end-stage renal disease programs as a whole.

*Histocompatibility complex are antigenic systems genetically controlled which play an important role in determining acceptance or rejection by the host of transplanted organs.

References:

1. Opelz, G. Sengar, DPS, et al: Effect of Blood Transfusions on Subsequent Kidney Transplants. Transplant Proc. 5:253, 1973.

2. Opelz, G. and Terasaki, P.I.: Importance of Pre-operative Transfusions for Cadaver Kidney Transplants. Transplantation 31:106, 1981.

3. Kung, PC, Tlla, MA et al: Strategies for Generating Monoclonal Antibodies Defining Human T Lymphocyte Differentiation Antigens. Transp. Proc. 12 (Suppl I) 141:12, 1980.

4. Corry, R.J.: 5 R01 AM 29863-02, University of Iowa, Iowa City, "Mechanisms of Transfusion in Improving Allograft Survival."

II. PATHOPHYSIOLOGY OF CHRONIC RENAL FAILURE

The kidney normally functions as an excretory organ maintaining exact balance of fluids and electrolytes. It has the ability to regulate urinary acidification through excretion of acid or alkali essential to normal acid-base homeostasis. Together, the kidney and respiratory system determine the pH of the plasma, interstitial fluid, and indirectly that of the cell content, therefore, governing the most important body metabolic functions. Lastly, the kidney functions as an endocrine organ, participating in the production of erythropoietin and in the active metabolization of vitamin D. Every facet of renal function is markedly deranged in the end stage of chronic renal disease and many organ systems are affected when the kidney fails, regardless of the type of treatment instituted, because of the uremic state per se. Examples of these complications include: anemia, renal osteodystrophy, increased susceptibility to infection, central and peripheral nervous system symptoms, cardiovascular complications, gastrointestinal disorders, sexual dysfunction, endocrine abnormalities, etc.

Examples of advances in our understanding of the underlying mechanisms leading to the complications of uremia are listed next.

1. REDUCED RENAL FUNCTION LIMITS METABOLISM OF PARATHYROID HORMONE, LEADS TO METABOLIC ACIDOSIS AND TO DERANGEMENTS OF CALCIUM/PHOSPHORUS METABOLISM FACILITATING THE DEVELOPMENT OF METABOLIC BONE DISEASE.

A high incidence of bone disease is known to occur in chronic renal failure patients and those on maintenance hemodialysis. An association between renal disease with derangements of calcium and phosphorus metabolism, hyperplasia (increased size and overfunction) of the parathyroid glands, and bone disease of all degrees has been recognized for years, but interest in this area has increased only in recent years.

- In studies designed to define the underlying mechanisms of the metabolic bone disease of chronic renal failure, investigators examined the effect of acute acidosis on the uptake of parathyroid hormone (PTH) and cyclic AMP (cyclic compound which mediates PTH action in bone and kidney) production by isolated perfused bone and showed that metabolic acidosis caused both an increase in the extraction of PTH and in the release of cyclic AMP. Changes in carbon dioxide (CO_2) which is produced metabolically but regulated by the lungs *per se* did not lead to changes, which suggests that acute metabolic acidosis increases bone reabsorption by increasing the uptake of PTH and cyclic AMP production by the skeleton (1).

- The role of the liver and kidney in the metabolism of intact PTH was studied with new methods. Results indicate that liver and kidney account for all of the degradation of intact PTH while bone only extracts a limited fraction of the PTH molecule. Reduction in renal mass, therefore, markedly reduces the peripheral metabolism of PTH both in the kidney and liver (1).

o Other studies, comparing also the roles of the kidney and liver in handling or metabolizing other hormones (i.e., insulin, glucagon, and somatostatin), are underway at present. Preliminary experimental data (2) show that the liver accounts for more than two-thirds of the overall degradation of insulin, glucagon, and somatostatin in canines. It is interesting to note that the mode of handling of these hormones by both organs is strikingly similar, but the kidney also is involved in filtration, hormone uptake, and inactivation of the hormones from blood that has previously filtered through the kidney glomeruli.

o Myocardiopathy (disease of the heart) was found to be related to excess PTH in uremia which is mediated by significantly enhanced myocardial calcium influx and uptake, reduced cellular (mitochondrial) oxygen comsumption, and impaired energy transport and utilization as shown by levels of myocardial ATP and creatinine phosphate (compounds, both directly governing energy production at cellular level).

o These recent research advances are steadily leading to a much better understanding of the underlying mechanisms leading to the many complications and systemic abnormalities of uremia. With further advance in our knowledge, therapeutic procedures and other conservative measures may be developed with the aim to prevent or ameliorate such complications of chronic renal insufficiency.

References:

1. Klahr, S: 5 PO1 AM 09976-17, Washington University, St. Louis, Missouri, "Pathophysiology of Renal Disease and Uremia."

2. Emmanouel, DS: 5 RO1 AM 19250-07, University of Chicago, Chicago, Illinois, "Endocrine Abnormalities in Uremia."

3. Massry, S.G.: 5 RO1 AM 29955-01, University of Southern California, Los Angeles, California, "Parathyroid Hormone and Uremia."

2. NEPHROTOXICITY OF PHOSPHATE IS GREATLY ENHANCED WITH DECREASED RENAL FUNCTION

Phosphate restriction may prevent further loss of kidney function in patients with advanced renal failure.

With advanced renal failure, dietary phosphate retention and hyperphosphatemia (increased level of phosphate in blood) contribute greatly to various clinical and biochemical abnormalities observed in uremic patients.

Studies of renal histologic changes on experimental animal models of chronic renal failure maintained on diets of varying phosphate contents were conducted (1). Rats on the higher phosphate diets had higher serum calcium and showed more calcification in the kidneys than those maintained on lower phosphate diets. It was also observed that the renal calcium content was much greater in kidneys removed from chronic renal failure patients, than in normal kidneys.

These findings lend support to the hypothesis that higher phosphate diets may accelerate loss of kidney function in renal failure through renal calcification occurring in the course of renal failure. Preliminary data suggest that neither parathyroid hormone (PTH) nor renal parenchymal calcification are responsible for the initiation of progressive renal failure, although it appears that these factors gain importance later in the course of renal failure (1).

Another group of investigators (2), working with experimental animal models of chronic renal insufficiency, develped the concept that the limited ability to handle acute loads of sodium, potassium, or phosphorus seen in the initial stages of renal insufficiency results in prolonged abnormalities of electrolyte and water homeostasis which reverts to normal later on. But as renal function further deteriorates, these derangements are more and more prolonged. Clinical experience indicates that this concept may also be applicable to human subjects.

Therefore, it appears that phosphate restriction and limitation of acute loads of electrolytes could prevent or arrest progression of renal failure. It seems to be an effective means of preventing further alteration of kidney function as proven experimentally in glomerulonephritis and in the nephrotic syndrome.

Studies should proceed to further clarify these concepts with the belief that early and correct nutritional interventions in the CRF patient population may lead to improved management and improved prognosis.

References:

1. Alfrey, A.C.: 5 RO1 AM 26095-04, University of Colorado Health Sciences Center, Denver, Colorado "Phosphate Toxicity in End-Stage Kidney Failure."

2. Bourgoignie, J.J.: 5 RO1 AM 19822-06, University of Miami, Florida, "Renal Failure: Pathophysiology and Possible Prevention."

3. RELATIONSHIP OF DIETARY PROTEIN INTAKE, POORLY CONTROLLED DIABETES MELLITUS AND POSSIBLE HORMONAL ACTIONS UPON RATE OF PROGRESSION OF RENAL DISEASE

While the literature over the past 50 years contains studies about diet and renal disease, little progress has been made towards indicating possible pathophysiologic mechanisms to explain effects of dietary metabolic alterations on kidney disease.

A comprehensive hypothesis which might explain the progressive deterioration in kidney function seen not only with renal disease but also with so-called "normal aging" has been developed by Dr. Brenner and colleagues at Peter Bent Brigham Hospital. Observations about the effect of dietary proteins on "renal work," made about 40 years ago by Addis, and subsequent data about dietary and metabolic effects and kidney adaptation, figure in this hypothesis along with a caution that high-protein diets of developed countries may have a deleterious effect on renal function in health and in various kidney diseases.

In an animal remnant kidney model, functional and structural changes have been shown to vary in relation to dietary protein levels. Glomerular disease (focal glomerular sclerosis) may develop and progress in relation to renal function and dietary protein. Similar responses in proteinuria, decreased renal function, and structural changes were noted in well controlled streptozotocin diabetic animals as compared to control diabetic animals. Macromolecular tracer studies showed that the proteinuria was attributable to defects in both charge-selective and size-selective properties of the glomerular capillary wall. It is postulated that the progressive azotemia, proteinuria, and glomerular sclerosis occurring after renal ablation are due to substained "adaptive" increases in glomerular blood vessel pressure and flow rate, possibly secondary to pharmacologic effects of a hormone such as glucagon. Protein excretion and renal pathologic changes were greater when dietary protein content was higher. Survival was significantly better in the rats on low protein diet.

The adaptive hyperfunction of glomeruli that results fron intrinsic renal disease or from extensive ablation ultimately may hasten the progression to renal failure in patients and in animals. Glomerular hyperfiltration which precedes loss of nephrons in the diabetic state may contribute to the initiation and progression of diabetic glomerulopathy noted in up to 70 percent of juvenile (Type I) diabetic patients. Similar glomerular hyperfunction in rats made diabetic with streptozocin and in rats partial-to-5/6 nephrectomized, appears to be caused by initial intrarenal vasodilatation, followed by increases in glomerular capillary pressures and flows.

These hypotheses suggest that therapies aimed at preventing excessive increases in glomerular pressure and flows could be introduced as a means to interrupt the relentless downhill progression of chronic renal diseases. An expansion of studies in the area of hyperfiltration and the contribution of metabolic control (protein, carbohydrates in diabetes, etc.) in slowing progression of renal failure may provide a key to treatment of the phenomena observed in "slow rejection" of renal transplant, in the downhill course of some patients with "inactive" glomulonephritis, in focal glomerulosclerosis, and in diabetic nephropathy.

References:

Brenner, B.M., 5 RO1 AM 19467-07, "Control of Fluid Exchanges on the Mammalian Kidney," Peter Bent Brigham Hospital, Boston, Massachusetts.

Hostetter, T.H., 5 KO8 AM 00767-02, "Renal and Peripheral Microcirculation in Diabetes," Peter Bent Brigham Hospital, Boston, Massachusetts and 1 RO1 AM 31437-01, "Glomerular Microcirculatory Response to Renal Injury," University of Minnesota, Minneapolis, Minnesota.

Hostetter, T.H., Olson, J.L., Rennke, H.G., Venkatachalam, M.A., Brenner B.M. Hyperfiltration in remnant nephrons; a potential adverse response to renal ablation. Am. J. Physiol., 1981, 241:F85-93.

Olson, J.L., Hostetter, T.H., Rennke, H.G., Brenner, B.M., Venkatachalam, M.A. Altered charge and size selective properties of the glomerular wall: a response to reduced renal mass. Kidney Int. 1979; 16:857 (abst.)

Hostetter, T.H., Rennke, H.G., Brenner, B.M. Compensatory renal hemodynamic injury: a final common pathway of residual nephron destruction. Am. J. Kidney Dis, 1982; 1:310-4.

Hostetter, T.H., Rennke, H.G., Brenner, B.M. The case for intrarenal hypertension in the initiation and progression of diabetic and other glomerulopathies. Am. J. Med. 1982; 72:375-80.

Hostetter, T.H., Troy, J.L., Brenner, B.M. Glomerular hemodynamics in experimental diabetes. Kidney Int. 1981; 19:1410-5.

4. TRACE ELEMENT ABNORMALITIES FOUND IN CHRONIC UREMIC PATIENTS ARE THE CONSEQUENCE OF THE UREMIC STATE PER SE

The toxicity of retained aluminum in uremic patients has been reasonably well established in the past few years. Brain aluminum content has been found to be significantly higher in patients dying of dialysis encephalopathy (dialysis dementia) as compared to patients dying of other causes. A strong association has been also found between aluminum and bone disease which occurs in some dialysis patients. The clinical importance of other trace element alterations found in uremic patients remain to be elucidated. (Trace elements are elements required in minute quantities which are provided in needed amounts by adequate routine diets. Examples are flouride, iodide, iron, zinc, copper, etc.)

A number of investigators have reported low plasma zinc levels in uremic patients (1-2), and it has further been reported that zinc administered to uremic patients improves appetite, sense of well being, and sexual function. Other investigators have been unable to confirm these findings (3).

Recently trace element profiles have been characterized in 29 nondialyzed uremic patients, 120 dialyzed patients and 52 control subjects (4). A number of trace element alterations were found in uremic patients such as total body zinc, tin, strontium and aluminum found to be increased; rubidium was decreased; iron was increased in liver and spleen; copper was increased in lungs and reduced in hearts of uremic patients.

It would appear that most trace element disturbances that occur in uremic patients are a consequence of the loss of renal function rather than induced by dialysis.

Since a number of these elements have been shown to be toxic, it cannot be concluded that their retention in renal failure is of no clinical importance. Futher investigations are still required in this area to clarify the clinical importance of the other element alterations found in uremic patients.

References:

1. O'Nion, J.V., Atkin-Thor, E., et al: Effect of Zinc Supplementation on Red Blood Zinc, Serum Zinc, Test Acuity, and Dietary Intake in Zinc Deficient Dialysis Patients. Dialysis Transp 7:1208, 1978.

2. Antoniou, L.D., Sudhakar, T et al: Reversal of Uraemic Impotence by Zinc. Lancet 2:895, 1977.

3. Brook, L.D., Johnston, D.B. et al: Absence of a Therapeutic Effect of Zinc in the Sexual Disfunction of Hemodialyzed Patients. lancet 2:618, 1980.

4. Alfrey, A.C, Smythe, WR: Trace Element Abnormalities in Chronic Uremia. Contract NO1 AM 4-2217.

5. NEPHROTOXICITY OF LITHIUM

The efficacy of lithium salts in the treatment of neuropsychiatric disorders and their increased use have resulted in renewed interest in the nature of the renal tubular toxicity, chronic tubulo-interstitial nephritis, and progressive renal insufficiency caused by these alkali salts.

The site of the early pathologic lesion and its correlation with the lithium-induced concentrating defect and polyuria have been reported. It produces structural cell changes accompanied by alterations of cell volume in the outer cortical collecting duct and the inner medullary collecting duct. Preliminary results of a prospective clinical study indicate that there is no definitive decrease in glomerular filtration rate in patients on lithium therapy.

Future directions: Retrospective evaluation and prospective studies to provide objective natural history data on patients treated with lithium chloride on a prolonged basis are needed. Animal studies are also needed to find a suitable therapeutic regimen to prevent kidney injury caused by chronic administration of lithium salts.

References:

R. T. McCluskey, 5 RO1 AM 18729-07, "Immunopathogenic Mechanisms in Renal Disease," Massachusetts General Hospital, Boston, Massachusetts.

G. G. Giebisch, 5 PO1 AM 17433-09, "Cardiovascular and Metabolic Aspects of Membrane Transport," Yale University School of Medicine, New Haven, Connecticut.

M. Kling, J. Fox, S. M. Johnston, N. Tolkoff-Rubin, R. Rubin and R. Colvin, "Toxicity of Lithium on the Kidney," (Progress Report).

Forrest, J. N., Marcy, T. U., Biemesberfer, D. and Kashgarian, M. "Cytoskeletal Defect in Cortical Collecting Duct Cells in Lithum-Induced Polyuria," Kidney Intl. (Abst.), 190: 200, 1981, (Yale).

6. PURIFICATION OF HUMAN URINARY ERYTHROPOIETIN, AND DEVELOPMENT OF A HIGHLY SPECIFIC RADIOIMMUNOASSAY

Erythropoietin (Ep) is the most important factor stimulating and controlling the production of red blood cells by the bone marrow; it is produced by the kidney. Nearly all patients being treated for chronic renal failure in the USA develop anemia due to the loss of kidney function and resulting absence of Ep synthesis. Although it is known that Ep is a glycoprotein of a medium molecular weight, little is known about its detailed structure, as well as to whether the active form of Ep is generated intact or activation is achieved only through a series of metabolic modifications. Because of the difficulties with previous assays, and the unavailability of pure Ep, these uncertainties, as well as the physiological and hormonal action of Ep, have been very difficult to study.

It is believed that an understanding of the structure and function of Ep would allow the development of techniques for manufacturing Ep on a large enough scale to make it available for administration to chronic renal failure patients as a replacement therapy.

Pure human Ep has been obtained from human urine by the use of hydrophobic chromapotagraphy (to exclude water) and of lectins (plant materials) attached to columns to render them stationary. As a result of improvements in technology, the purification of Ep has been simplified greatly, although the yields obtained still need improvement.

With the isolation of pure Ep, it became possible to develop a radioimmune assay specific for Ep, and sensitive enough to detect it in extremely small amounts. The radioimmunoassay involves the production of specific antibodies to pure Ep, and incorporation of radioactivity into the antibodies to facilitate detection in small amounts. With this method, the amounts and sites of cellular function can be measured directly and accurately for the first time.

Since virtually nothing is known at present about the mechanism of action of Ep at the cellular level, it will now be possible to establish the sites and characteristics of membrane surface receptors for Ep, conditions under which cells are responsive to Ep, and its action on intracellular events in both normal hemopoiesis and hemopoietic diseases. Of considerable interest is the anemia of renal insufficiency, where it will be possible to examine the proposed role of Ep in enhancing red blood cell synthesis in these patients.

Research should continue to improve the yields of pure erythropoietin, and determine its structure; to locate the region on the human chromosome which codes for erythropoietin; and to study the mechanisms and cellular sites of biogenesis of erythropoietin.

References:

1. Judith B. Sherwood, Ph.D., 1 R23 AM 31524-01 Albert Einstein College of Medicine.

2. Goldwasser, E. aand J.B. Sherwood, Annotation: Radioimmunoassay of Erythropoietin, Brit. J. Haematol. 48:359-363, 1981.

EXERCISE TRAINING BY HEMODIALYSIS PATIENTS PRODUCES BENEFICIAL EFFECTS ON LIPID AND CARBOHYDRATE METABOLISM

Cardiovascular complications are among the leading causes of premature death in ESRD patients on maintenance hemodialysis therapy.

Endurance exercise training has proven to exert significant beneficial effects on many coronary risk factors in non-uremic individuals. It reduces plasma triglyceride and cholesterol levels, increases plasma high density lipoprotein cholesterol concentrations, improves glucose tolerance, and increases insulin sensitivity.

Under NIADDK support a longitudinal study with hemodialysis patients randomly assigned to an immediate exercising program or to sedentary control has been conducted.

Exercise training in hemodialysis patients appears to improve lipid profiles, glucose metabolism, lower blood pressure, lessen requirements for hypertensive drugs, improve hematological functions, increase the level of physical fitness, and improve the patient's mood and certain psychological functions.

Participation in aerobic endurance exercise programs seems to improve some of the metabolic abnormalities observed in ESRD patients on maintenance hemodialysis, and may reduce the risks for cardiovascular complications. Further clinical as well as experimental studies should proceed to further verify observations and elucidate basic mechanisms leading to these benefical changes.

Reference:

Goldberg, A.P.: Contract No. NO1 AM-9-2221, Washington University, St. Louis, Missouri, "Effects of Exercise Training on Lipid and Carbohydrate Metabolism in Hemodialysis Patients."

C. ESRD Network Organizations

Introduction

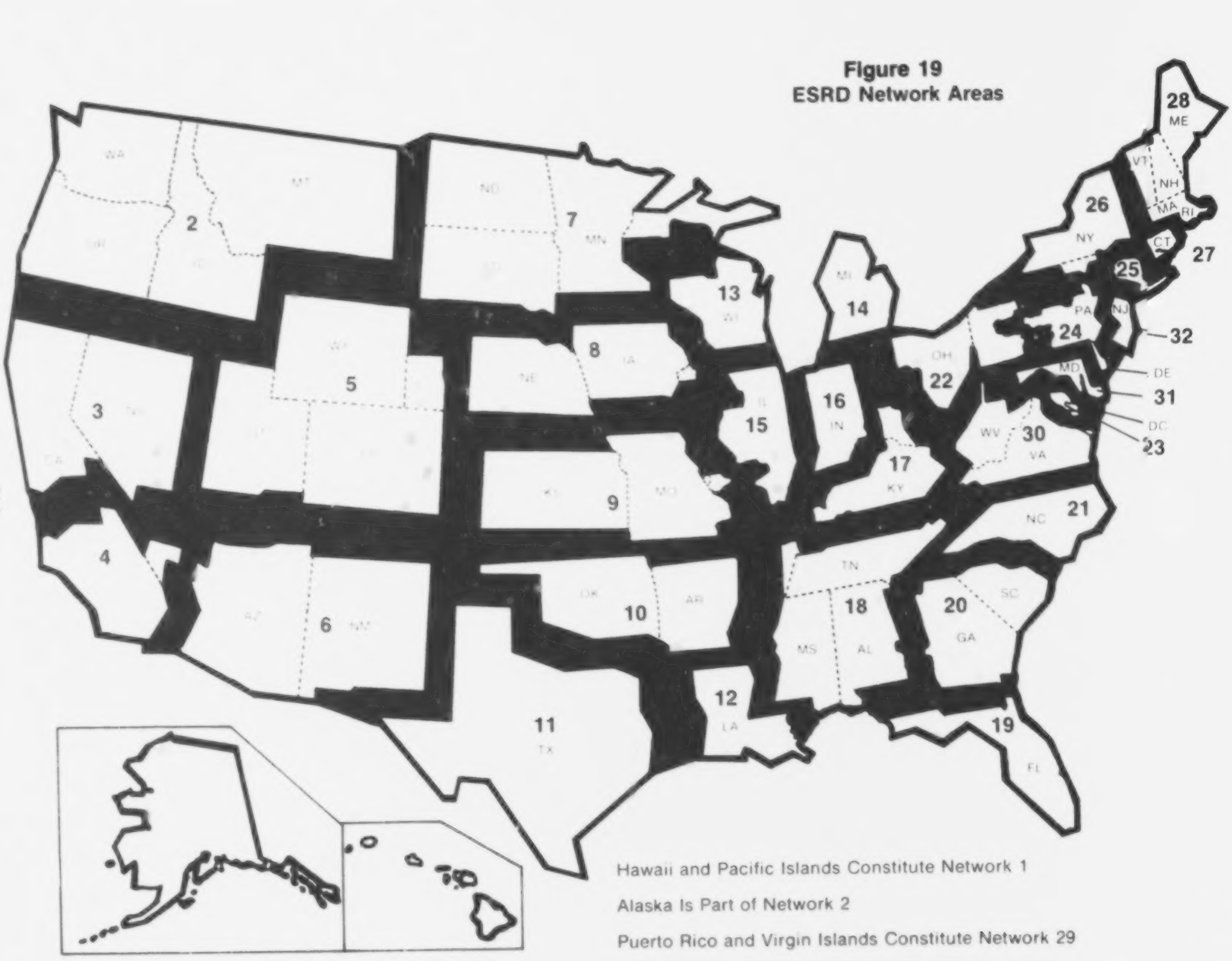
The objectives of the ESRD program are to promote high quality care and the efficient distribution of resources in the delivery of kidney dialysis and transplantation services. Section 1881 of the Social Security Act authorized the establishment and support of Network organizations to accomplish this purpose. There are 32 Network organizations (see Figure 19) composed of representatives from each dialysis and transplant facility as well as at-large members representing ESRD patients and professional disciplines (such as social workers, nurses, dieticians, etc.) involved in the delivery of ESRD services. Total funding for the Networks during 1982 was approximately $5 million. The Department remained opposed to the continuation of Networks and again proposed that all Networks be abolished.

Accomplishments

Network efforts during 1982 focused on quality assurance, data collection, rehabilitation of patients, planning for new, or the expansion of existing, services, and special studies in each of the Networks on various aspects of ESRD. Networks continued to work to meet the Congressionally mandated goals of encouraging home dialysis and transplantation. Although the Network role in the facility certification and approval process is limited to recommending on the need for new or expanding services, many Networks were actively engaged in on-site review of patient care.

Quality assurance and data management continued to be the major thrust of all Networks. Patient tracking systems have been implemented in most Networks which have enhanced their ability to validate data and to identify areas of further study.

Figure 19
ESRD Network Areas


28
ME
VT
NH
MA
RI
27
CT
26
NY
25
PA
NJ
24
32
DE
MD
31
DC
23
WA
MT
2
OR
ID
ND
7
MN
13
WI
MI
14
WY
5
NE
8
IA
3
CA
NV
UT
CO
15
IL
16
IN
OH
22
WV
30
VA
17
KY
KS
9
MO
NC
21
4
TN
OK
10
AR
18
20
SC
AZ
6
NM
MS
AL
GA
12
LA
11
TX
19
FL

Hawaii and Pacific Islands Constitute Network 1

Alaska Is Part of Network 2

Puerto Rico and Virgin Islands Constitute Network 29

D. APPENDIX - TABLES AND FIGURES

Table 1 ESRD Facilities Surveyed and Reporting by State

Table 2 Minimum Utilization Rate Status - Transplant

Table 3 Annual Distribution of Self-Care Dialysis Patients

Table 4 Patients Receiving Care As of 12/31/82

Table 5 Number and Percent Increase of Dialysis Patients

Table 6 Transplants Performed During 1982 - By State

Table 7 Range of the Numbers of Transplants Performed for 1982

Table 8 ESRD Network Distribution of Transplants Arrayed by Number of Transplants Performed

Table 9 Charges, Estimated Reimbursements and Average Length of Stay for Transplants and Nontransplant Hospital Stays : 1980

Table 10A Kidney Acquisition Charges - Average and Range for Living Related Donor Kidneys for 1982 By Region

Table 10B Kidney Acquisition Costs - Average and Range of Estimated Costs for Living Related Donor Kidneys for 1982 by Region

Table 11A Kidney Acquisition Charges - Average and Range for Cadaveric Donor Kidneys for 1982 by Region

Table 11B Kidney Acquisition Costs - Average and Range of Estimated Costs for Cadaveric Donor Kidneys for 1982 By Region

Table 12 1982 Kidney Acquisition Costs Reported By Independent Organ Procurement Agencies by Region

Table 13 Exception Requests Processed in 1982

Table 14 Estimated Enrollment and Aggregate Benefit Payments on a Cash Basis, Total ESRD Medicare Program

Table 15 Estimated Income to Medicare Generated by ESRD Second Payer Regulation

Table 16 Medicare Eligibility Status of Patients Being Treated By Medicare Certified ESRD Facilities

Table 17 Medicare ESRD Program Incidence By State, All Persons and White Over Age 65, 1978 to 1980 Average

Table 18 Medicare Program Incidence Rates, By State Distribution: 1978 - 1980

Table 19 Mortality Rates (Per 1,000 ESRD Dialysis Patients, Per Year) for the Dialysis Study Population Whose Date of First Reported Dialysis was 9/73 or Later, Followed to Death, Transplant, or 9/81, By Age, Race, and Sex, and Adjusted for These Factors

Table 20 Modified Life Table Analyses for the Dialysis Study Population Whose First Dialysis Was 9/73 or After (Follow-up is to Death, Transplant, or 9/81)

Table 21 Mortality Rates (Per 1,000 ESRD Transplant Patients, Per Year) for the Renal Transplantation Population Whose Date of First Reported Transplant was 7/73 or Later, Followed to Death, Date of Transplant Failure Plus 3 Months, Termination of Entitlement, or 9/81, by Age, Race, and Sex, and Adjusted for These Factors

Table 22 Modified Life Table Analyses for the Renal Transplantation Population Whose First Transplant was 7/73 or After (Follow-up is to Death, Date of Transplant Failure Plus 3 Months, Termination of Entitlement, or 9/81, Whichever Occurred First)

Table 23 Patient Survival Rates for the Various Demographic Categories

Table 24 Graft Retention Rates for the Various Demographic Categories

Table 25 Patient Survival Rates by Year of Onset of Treatment

Table 26 Graft Retention Rates by Year of Transplantation

Table 27 Hospitalized Persons by Number of Hospitalizations, 1980 and 1981

Table 28 Hospitalization Rates for Medicare ESRD Beneficiaries by Age, Sex, and Race; 1980 and 1981 (Including Transplant Patients)

Table 29 Hospitalization Rates for Medicare ESRD Beneficiaries by Age, Sex, and Race; 1980 and 1981 (Excluding Transplant Patients)

Table 30 Hospitalization Rates for Medicare Aged, Disabled and ESRD Beneficiaries

Table 31 Ratio of Patients Trained for Home Dialysis and Dialysis Patients Transplanted to Average Number of Dialysis Patients, January 1979 - December 1982)

Figure 1 ESRD Program Growth
Figure 2 Number of Certified ESRD Facilities
Figure 3 Dialysis Facilities, Hospital - 1982
Figure 4 Dialysis Facilities, Independent - 1982
Figure 5 Type of Ownership - Profit vs. Non-Profit, 1171 ESRD Dialysis Providers, 1982
Figure 6 Minimum Utilization Rate Status, Dialysis - 1982
Figure 7 Number of Patients in Each Dialysis Treatment Setting By Network - 1982
Figure 8 Home Dialysis Patients - 1982
Figure 9 Home Dialysis Modality - 1982
Figure 10 Home Patient Modalities (Hemodialysis, Peritoneal and CAPD)
Figure 11 Number of Chronic Dialysis Patients Being Treated By Medicare Certified Suppliers of ESRD Services in the United States By Treatment Setting, January 1979 - December 1982
Figure 12 Dialysis Setting 1981 - 1982
Figure 13 Number of Transplant Types By Network - 1982
Figure 14 Transplants 1981 - 1982
Figure 15 Patients Awaiting Transplants vs. Transplants Performed
Figure 16 Comparison By Region of Exception Requests - 1982
Figure 17 Comparison By State of Exception Requests - 1982
Figure 18 Major Reasons for Changes in the Number of Patients Treated By Medicare Certified Suppliers of ESRD Services, 1979 - 1982
Figure 19 ESRD Network Areas

☆U.S. GOVERNMENT PRINTING OFFICE: 1986 • 491 - 263 - 53402

Department of
Health and Human Services
Health Care Financing Administration
HCFA Pub. No. 02157